IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION	**Master Docket: No. 21-mc-1230-JFC**
	MDL No. 3014
	(Oral Argument Requested)
This Document Relates to:	
Amended Master Long Form Complaint For Personal Injuries And Damages, And Demand For Jury Trial (ECF No. 834)	

REPLY MEMORANDUM IN SUPPORT OF PHILIPS RS NORTH AMERICA LLC'S MOTION TO DISMISS

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TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

Statutes

Other Authorities

ARGUMENT

I. PLAINTIFFS CANNOT AVOID THE STRUCTURAL DEFICIENCY OF THE PIAC AND SHORT FORM COMPLAINTS.

The parties agree, and PTO 28 expressly provides, that the Amended Master Long Form Complaint for Personal Injuries and Damages (ECF No. 834) (the "PIAC") and Short Form Complaint ("SFC") taken together constitute an individual personal injury plaintiff's operative complaint. ECF No. 1594 at 5. Philips RS North America LLC ("Respironics") argued in its Moving Brief ("MTD") that the PIAC and SFC are deficient because the Master SFC Plaintiffs drafted does not require individual plaintiffs to plausibly allege that: (1) the individual plaintiff's device manifested a defect; (2) foam degradation exposed the plaintiff to harmful amounts and concentrations of emissions; and (3) such exposure caused physical injury. Without such allegations, the PIAC and SFCs fail to allege causation and should be dismissed.

Instead of grappling with this fundamental flaw, Plaintiffs Brief in Opposition ("Opposition" or "Opp.") urges the Court to defer evaluation of their pleadings until after discovery (Opp. at 6), or maybe until after bellwether selection (Opp. at 8), or maybe until after *Daubert* motions (Opp. at 10), or maybe even until after all cases have been transferred to their home districts (Opp. at 8)—as long as it is not ***now***. This theme of delay pervades Plaintiffs' Opposition—Plaintiffs cannot defend their claims from dismissal, so they ask the Court to avert its eyes and defer the inevitable. Plaintiffs' proposed approach is inconsistent with the Federal Rules. Considerations of efficiency and preservation of resources counsel strongly against allowing a flood of individual plaintiffs who cannot even allege a plausible claim into the case. Plaintiffs' arguments do not compel a different conclusion.

First, Plaintiffs criticize Respironics for having the "temerity" to challenge "the processes it agreed to," but Respironics is not challenging the PIAC ***process***. Opp. at 5-6. Respironics did

not participate in the preparation of or approve the content of the SFC. The parties and the Court have always understood that Respironics intended to test the PIAC's ***allegations***. That is why PTO 28 states that "[b]y agreeing to the procedures for filing the Amended Master Personal Injury Complaint and the Short Form Complaints, no Defendant has agreed to or admitted the allegations that will be set forth in those documents, nor has any Defendant conceded or waived its rights to dispute the legal validity of the claims alleged therein." ECF No. 1594 at 9-10. PTO 28 makes clear that neither Respironics nor the Court endorsed a process that would relieve individual plaintiffs' requirement to plausibly plead causation or any other required element of their claims: "Nothing in this Order is intended to (or does) alter the applicable provisions of the Federal Rules of Civil Procedure . . . ." *Id*. at 1.

Second, Plaintiff Fact Sheets under PTO 26 do not cure the deficiency (Opp. at 6) because they are "the same as interrogatory responses," not substitutes for pleading. ECF No. 871 at 3. "It is no answer to say that" insufficient SFCs "can be weeded out early in the discovery process," because a plaintiff who fails to state a plausible claim is not even entitled to participate in discovery. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 546 (2007).

Third, Plaintiffs' contention that MDL courts should not decide "case-specific issues" is a red herring because Respironics has made no case-specific arguments. Opp. at 8. Respironics' argument is that the PIAC together with the SFC fail to state a cause of action because the SFC neither requires nor invites individual plaintiffs to plead facts necessary to support their claims. Respironics has not asked the Court to pass on the specific allegations of any ***particular*** plaintiff's SFC. Moreover, while ***case-specific rulings*** may not be an MDL court's primary role, where, as here, an MDL master complaint supersedes and becomes an individual plaintiff's operative complaint, it is within the MDL court's function to require ***case-specific allegations*** needed to

state a plausible claim. *See In re Refrigerant Compressors Antitrust Litig.,* 731 F.3d 586, 590-91 (6th Cir. 2013) (where MDL master complaint supersedes and becomes the operative complaint, "the master complaint is examined for its sufficiency when the defendants file a motion to dismiss"). Cases like *In re Trasylol Prod. Liab. Litig*., No. 08-MD-1928, 2009 WL 577726, at *8 (S.D. Fla. Mar. 5, 2009), *In re Zimmer Nexgen Knee Implant Prod. Liab. Litig*., No. 11C5468, 2012 WL 3582708, at *3 (N.D. Ill. Aug. 16, 2012), and *In re Nuvaring Prods. Liab. Litig*., No. 08MD1964, 2009 WL 2425391, at *2 (E.D. Mo. Aug. 6, 2009), are inapposite. In each case the master complaint was intended to serve a purely administrative function and did not supersede and become the plaintiffs' operative complaint. That is not the case here. *See Refrigerant Compressors Antitrust Litig.*, 731 F.3d at 591.

Fourth, Plaintiffs assert the PIAC's generalized allegations alone show that the individual plaintiffs "are precisely those users whose Devices contained foam that degraded and off-gassed, releasing particles and causing Plaintiffs to sustain injuries." Opp. at 2. But this assertion appears nowhere in the PIAC. To the contrary, the PIAC alleges just the opposite—that "users had no way of knowing themselves that foam in their Devices had degraded or off-gassed toxins." PIAC ¶ 144. Plaintiffs' similar argument that the Court should infer from the PIAC's general allegations that individual plaintiff's "use of the Devices caused them to suffer serious health effects" (Opp. at 3) likewise fails because abstract allegations on behalf of all individual plaintiffs ***generally*** cannot possibly state a plausible claim on behalf of a ***specific*** plaintiff—that is why proper SFCs are necessary.[1]

[1] Plaintiffs' argument that their claims under the laws of states in which no individual plaintiff lives should not be dismissed wrongly assumes that the Court may consider the purported existence of some 30,000 people who may or may not file claims someday when evaluating the sufficiency of the complaint. Opp. at 7. ***Hypothetical*** plaintiffs provide no basis to preserve claims under the laws of states with no connection to any ***actual*** plaintiff.

Finally, Plaintiffs' plea that if the Court finds the PIAC and SFC lacking "the proper remedy would be to direct Defendants to file a motion for an order requiring Plaintiffs to replead pursuant to Rule 12(e)" makes no sense. Opp. at 10 n.15. "Motions for a more definitive statement . . . are used to provide remedies for unintelligible pleadings rather than as correction for lack of detail." *Godfrey v. Upland Borough*, 246 F. Supp. 3d 1078, 1086 (E.D. Pa. 2017). If the Court finds, as it should, that the PIAC fails to state a claim, then the proper remedy is dismissal.[2]

II. PLAINTIFFS HAVE NOT MET THE LEARNED INTERMEDIARY DOCTRINE PLEADING REQUIREMENTS.

To plead causation under the learned intermediary doctrine, Plaintiffs must allege their physicians would have made different prescribing decisions if adequately warned. MTD at 10-12. Where Plaintiffs "fail[] to sufficiently allege that an adequate warning would have altered the conduct of Plaintiff's physician," they have "not sufficiently alleged causation." *Roshkovan v. Bristol-Myers Squibb Co.*, No. EDCV218590, 2022 WL 3012519, at *9 (C.D. Cal. Jun. 22, 2022). Citing inapposite cases,[3] Plaintiffs attempt to breeze past scrutiny of their pleading to dispute the adequacy of any warnings, Opp. at 10-12, but the doctrine does not "suddenly become[] inapplicable when a plaintiff alleges that warnings are inadequate." *Sanchez v. Bos. Sci. Corp.*, 38 F. Supp. 3d 727, 734 (S.D. W. Va. 2014). Plaintiffs must "plead facts that would show [that] but for those inadequacies [their] doctors would have recommended different treatment." *Miles v.*

[2] If Plaintiffs are permitted to replead, they should be ordered to draft a revised Master SFC that requires individual plaintiffs to plausibly plead causation, and individual plaintiffs should be required to execute the new SFCs if they can do so consistent with their Rule 11 obligations.

[3] *Walton v. Bayer Corp.*, 643 F.3d 994, 999-1002 (7th Cir. 2011), examines whether the learned intermediary doctrine creates a common defense exception that would prevent a determination of fraudulent joinder; *Green v. Ethicon, Inc.*, 497 F. Supp. 3d 364, 370 (C.D. Ill. 2020), denies summary judgment because an issue of material fact existed as to the sufficiency of defendants' warnings; and in *Baker v. Bayer Healthcare Pharms., Inc.*, No. C13-0490, 2013 WL 6698653, at *5 (N.D. Cal. Dec. 19, 2013), neither party raised the learned intermediary defense and plaintiff alleged she would not have used the drug had she received adequate warnings.

Bos. Sci. Corp., No. CV H 19-4319, 2020 WL 3871329, at *9 (S.D. Tex. Jul. 9, 2020).

Plaintiffs ask the Court to infer (Opp. at 11) that Plaintiffs' prescribing physicians would have changed their treatment decisions had they received an adequate warning, but fail to allege plausible facts that would make such an inference reasonable. *Harrison v. Medtronic, Inc.*, 561 F. Supp. 3d 698, 706 (N.D. Tex. 2021) ("Other than the unsupported assertion that a different product would have been used if Defendant had provided adequate warnings . . . Plaintiffs do not explain how Dr. Hebeler would have changed his treatment decision.").[4] Plaintiffs point to a repeated conclusory assertion, Opp. at 11 (citing PIAC ¶¶ 566, 583, 611), but the PIAC does not allege that any plaintiff's physician would have made a different decision if adequately warned and the SFC does not invite individual plaintiffs to fill this gap.[5] Plaintiffs' failure to allege, *inter alia*, causation under the learned intermediary doctrine, compels dismissal of their negligence, implied warranty, fraud, unjust enrichment, and state consumer protection law claims.

III. PLAINTIFFS CANNOT AVOID IMPLIED PREEMPTION.

Plaintiffs fail to provide the Court a basis to find their claims are not impliedly preempted.

Plaintiffs' misplaced argument that preemption is an affirmative defense is based on ***express*** preemption cases. Opp. at 12-15. Respironics' motion, however, is grounded in ***implied*** preemption, which this Court and others have held is a proper basis for dismissal under Rule 12(b)(6) where the grounds for preemption are alleged in the complaint. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-48 (2001) (finding "no presumption against pre-emption"); *Bell v. Boehringer Ingelheim Pharms., Inc.*, No. CV 17-1153, 2018 WL 2447788 at *6 (W.D. Pa. May

[4] *Harrison v. Medtronic, Inc.* was affirmed in part and reversed in part and remanded by the Fifth Circuit, but the lower court's ruling regarding the application of the learned intermediary doctrine was not appealed. No. 22-10201, 2022 WL 17443711 (5th Cir. Dec. 6, 2022).

[5] Plaintiffs' attempt to amend the PIAC through briefing is emblematic of the problem. Plaintiffs argue in their Opposition that "no reasonable doctor would have prescribed the Devices," but they cite nothing in the PIAC to back up their argument. Opp. at 12.

31, 2018) (Conti, J.). Implied preemption is evident from the face of the PIAC because its claims are improperly predicated on alleged violations of the FDCA and FDA regulations.

Plaintiffs' Opposition also ignores the controlling standard. To avoid implied preemption the "plaintiff must not be suing ***because*** the conduct violates the FDCA." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (*Buckman* left only a "narrow gap" to escape preemption). It also fails to sufficiently identify a "narrow legal theory" required to surmount implied preemption that this Court reiterated in *Bell.* "[F]or a state-law claim to survive [preemption] . . . the claim must be premised on conduct that would give rise to a recovery under state law even in the absence of the FDCA." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 493 (W.D. Pa. 2012) (Fischer, J.) (finding claims that "arise from generalized common theories of liability and not state statutes that provide a private cause of action for FDCA violations" do not fit into "exceptions to implied preemption"). Plaintiffs' contention that "the traditional state law duties violated by Philips also violate the FDCA," Opp. at 15, does not navigate the required narrow gap. The only duties Plaintiffs expressly allege arise under FDA regulations (PIAC ¶¶ 122-23; Opp. at 29-30) and "obligations imposed by FDA regulations. ¶¶ 125-27." Opp. at 3. The Third Circuit, relying on *Buckman*, rejected exactly such "attempt[s] to use a federal duty and standard of care as the basis for . . . [a] state-law negligence claim." *Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701, 716-17 (3d Cir. 2018); *see also Froman v. Coopersurgical, Inc.*, No. 22-CV-00110, 2022 WL 2657117, at *6 (N.D. Ala. Jul. 8, 2022) ("[R]eporting incidents of adverse events is a duty . . . owe[d] to the FDA instead of consumers. Consequently, all claims premised on the breach of this duty are squarely barred by the MDA's implied preemption provision."). Absent allegations of a preexisting independent state law duty, Plaintiffs' claims cannot traverse the "narrow gap" set out

by *Buckman* and its progeny, and dismissal on implied preemption grounds is required.

IV. PLAINTIFFS' NEGLIGENT RECALL CLAIMS SHOULD BE DISMISSED UNDER THE PRIMARY JURISDICTION DOCTRINE.

The PIAC repeatedly invokes the FDA's involvement in the recall, incorporating evidence of the FDA's active and ongoing oversight, and relying on the FDA's proposed order concerning "Device Repair, Replacement, and/or Refund," which set out the FDA's alleged intent to pass judgment on Respironics' recall efforts. *See, e.g.*, PIAC Ex. 72 (Section 518(b) Notice); *id.* ¶¶ 9, 16, 191, 297 n.408. The PIAC thus effectively admits that the FDA is the proper decision-maker to evaluate Plaintiffs' negligent recall claims under the primary jurisdiction doctrine.

Yet, as to the first and second *Baykeeper* factors, Plaintiffs urge the Court not to defer to the FDA because their "recall-related claim does not require specific expertise." Opp. at 18. Plaintiffs cannot have it both ways, and their contention is plainly contradicted by the FDA's determination that the remedial measures involved in the recall "may present significant risks," implicating the FDA's specific expertise. PIAC Ex. 72 (Section 518(b) Notice) at 12. Plaintiffs' argument also runs counter to this Court's observation that "courts are not to get involved with what the FDA does in regulating the matters that are subject to . . . its jurisdiction." Trans. at 9, Mot. to Dismiss Hr'g, *SoClean* (Feb. 21, 2023) (ECF No. 104).

As to the third and fourth *Baykeeper* factors, Plaintiffs do not dispute that the FDA is relying on its specific expertise to actively oversee and evaluate the recall, including the repair and replacement program. *See, e.g.*, PIAC ¶¶ 9, 16, 191 and Exs. 72, 136. Plaintiffs' claims challenging the manner Respironics is conducting the recall under FDA oversight will subject Respironics to potentially conflicting standards and determinations. *See id.* Ex. 72 (Section 518(b) Notice) at 2 (contemplating an order requiring Respironics "to submit a plan to repair, replace, and/or refund the purchase price for the recalled devices"). The FDA's past and ongoing oversight

of the recall, along with the other *Baykeeper* factors, weighs in favor of abstention.[6]

Plaintiffs' Opposition also incorrectly suggests that Respironics moved to dismiss the entire case on primary jurisdiction grounds, while Respironics argued only that recall-related claims within the special competence of the FDA are subject to the primary jurisdiction doctrine.[7] Plaintiffs' reliance on *SoClean* is also inapposite, Opp. at 17 n.22. There, the Court expressed skepticism about the nexus between FDA's determination on SoClean's pending application and plaintiffs' claims. *See* Trans. at 27-40, Mot. to Dismiss Hr'g, *SoClean* (Jan. 25, 2023), annexed as Ex. 1 to the Opp. to Respironics' Motion to Dismiss the TAC[8] (ECF No. 1544-1). Here, however, deference to FDA's expertise is appropriate because the PIAC and its exhibits establish FDA's active oversight of the very matters that are the subject of Plaintiffs' recall-related claims.

V. TEN STATES DO NOT RECOGNIZE NEGLIGENT FAILURE TO RECALL.

Ten states do not recognize negligent failure to recall as an independent cause of action. MTD Section IV, Moving Citation Table ("CT") A(1). Plaintiffs concede the point for Indiana, Mississippi, Missouri, and Ohio. Opp. at 19 n.24 & Chart 1. The cases Plaintiffs cite for the other six states do not support a stand-alone negligent failure to recall cause of action. *See id.* at Chart 1. For example, Plaintiffs misplace reliance on *Lance v. Wyeth*, 85 A.3d 434, 459-60 (Pa. 2014), which discusses manufacturers' general duties under "the law of negligence," but says nothing

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[6] Plaintiffs rely on *Cohen v. Subaru of America, Inc.*, which states that initiation of a recall "***alone*** is insufficient to justify abstention." No. 20-cv-08442, 2022 WL 721307, at *37 (D.N.J. Mar. 10, 2022) (emphasis added). Here, however, all four factors weigh in favor of abstention.

[7] Plaintiffs' cases are distinguishable. *See In re MTBE Prods. Liab. Litig.*, 175 F. Supp. 2d 593, 618 (S.D.N.Y. 2001) (finding "none of [the] agencies [was] addressing the specific issues raised by plaintiffs' common law claims, nor [were] the[] issues squarely within their expertise"); *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, MDL No. 2875, 2020 WL 7418006, at *11-12 (D.N.J. Dec. 18, 2020) (recall claims not at issue). Plaintiffs' suggestion that 21 U.S.C. § 360h(d) greenlights all state-law claims, Opp. at 18, was rejected by the Supreme Court. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 n.4 (2008) (section 360h(d) "could not possibly mean that *all* state-law claims are not pre-empted").

[8] "TAC" refers to the Third Amended Complaint for Economic Losses (ECF No. 785).

about an independent negligent failure to recall claim. Plaintiffs' reliance on *Smith v. Howmedica Osteonics Corp.*, 251 F. Supp. 3d 844, 853 (E.D. Pa. 2017) is likewise unavailing. Where a state's highest court or legislature has not articulated the elements of a claim, the district court must "opt for the interpretation that restricts liability, rather than expands it." *Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 253 (3d Cir. 2010). District courts "cannot invent new state law claims." *Banks v. E.I. du Pont de Nemours & Co.*, No. 19-1672, 2022 WL 3139087, at *9 (D. Del. Aug. 4, 2022). Plaintiffs' negligent failure to recall cause of action should be dismissed insofar as it is alleged under the laws of one of the ten states that do not recognize it.

VI. CERTAIN CLAIMS ARE SUBSUMED BY STATE PRODUCT LIABILITY ACTS.

Respironics showed that certain of Plaintiffs' claims are subsumed by certain states' PLAs. *See* MTD Section V & CT B(1-2). Plaintiffs' Chart 2 (Opp. at 20) does not alter that conclusion because it focuses, for example, on inapposite exceptions like financial injury, and on claims not alleged in the PIAC. *See* Reply Citation Table ("RCT") A(1).

As a fallback, Plaintiffs plea for delay by arguing PLAs do not eliminate common-law substantive rights but merge them into one statutory cause of action, and so the "proper remedy would be for Plaintiffs to amend the Master Complaint." Opp. at 20. But Plaintiffs assert no PLA claims in the PIAC so merger does not help them, and Plaintiffs should not be permitted to amend yet again to add new causes of action.[9] *See Mann v. Brenner*, 375 F. App'x 232, 240 n.9 (3d Cir. 2010). Plaintiffs also argue subsumption is too "state- and claim- specific" to be determined at this stage, but articulate no reason why such "specificity" prevents the Court from ruling now. *See e.g.*, *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, MDL No. 2875, 2021 WL 364663, at *13 (D.N.J. Feb. 3, 2021) (granting motion to dismiss claims subsumed by state PLAs.)

[9] Plaintiffs were aware of the PLAs when filing the PIAC–they pled PLA claims for the same states in the Second Amended Medical Monitoring Complaint ("MMSAC") ¶¶ 695-736 (ECF No. 834).

VII. PLAINTIFFS' EXPRESS AND IMPLIED WARRANTY CLAIMS FAIL.

A. Plaintiffs Allege Only a Design Defect.

Plaintiffs do not dispute they allege only a ***design defect***, not a *manufacturing defect*. *See* Opp. at 21-23. Nor do they dispute that in every jurisdiction except (arguably) one, "workmanship and materials" warranties like Respironics' warranty here cover only ***manufacturing defects***.[10] *See id.* at 21. Instead, Plaintiffs argue that the warranty is somehow ambiguous because a separate provision states that the devices "will perform in accordance with the product specifications." *See id.* Not so. The warranty's next sentence (which Plaintiffs ignore) affirms that it covers only manufacturing defects: "This warranty ***does not cover*** damage caused by . . . other ***defects not related to material or workmanship***." *See* PIAC Ex. 47 at 29 (emphasis added). This express disclaimer is dispositive of Plaintiffs' argument.

Plaintiffs alternatively plead for more delay and urge the Court to defer the issue until after discovery. Opp. at 23. But discovery cannot change the plain meaning of the warranty, which must be enforced as written. Moreover, Plaintiffs do not dispute that they continue to allege ***only*** a design defect even after already having obtained substantial discovery.[11] There is no reason to defer the inevitable and Plaintiffs' warranty claims should be dismissed. *See Sauer v. Subaru of Am., Inc.,* No. CV 18-14933, 2020 WL 1527779, at *6 (D.N.J. Mar. 31, 2020) (dismissing claim for breach of "workmanship and materials" warranty where there were "no allegations supporting

[10] Plaintiffs assert that certain states do not "preclude design defect claims when the warranty is for 'material and 'workmanship,'" but identify only Pennsylvania. Opp. at 21-22. "[T]he vast weight of authority," including in Pennsylvania, holds that "a workmanship and materials warranty cannot encompass a design defect claim." *Nelson v. Nissan N. Am., Inc.*, No. CIV. 11-5712, 2014 WL 7331922, at *3 (D.N.J. Dec. 19, 2014); *see also* RCT B(1). The cases Plaintiffs rely on are inapposite because they apply *Samuel-Bassett v. Kia Motors Am., Inc.*, 34 A.3d 1 (Pa. 2011), which did not analyze the meaning of "materials and workmanship."

[11] Plaintiffs' only case, *Winkworth v. Spectrum Brands, Inc.*, No. CV 19-1011, 2020 WL 3574687, at *4 (W.D. Pa. Jun. 30, 2020), does not help them because there the plaintiff alleged "defects in workmanship and materials as well as design defects." *See* Opp. at 23.

that the engine defect was also a manufacturing defect").[12]

B. Plaintiffs' Failure of Essential Purpose Argument Fails.

A Plaintiff may not avail himself of a failure of essential purpose argument absent allegations that, ***after giving a seller an opportunity to repair or replace*** an allegedly defective product, the seller either refused to repair or replace the product or failed to complete repairs within a reasonable amount of time. *See Demorato v. Carver Boat Corp*., 304 F. App'x 100, 103 (3d Cir. 2008), cited by Plaintiffs (Opp. at 23); *Midwest Printing, Inc. v. AM Int'l, Inc*., 108 F.3d 168, 171 (8th Cir. 1997). Plaintiffs fail to sufficiently allege that Respironics' "repair and replacement program failed its purpose" for two primary reasons:[13]

First, the PIAC does not allege Plaintiffs registered their devices for Respironics' repair/replacement program, and the SFC does not invite individual plaintiffs to fill that gap with individualized facts. *Demorato* explains that a purchaser cannot show failure of essential purpose absent allegations they gave a manufacturer the opportunity to repair or replace the allegedly defective product. 304 F. App'x at 103 ("[Plaintiffs] cannot cause the repair remedy to fail by refusing to avail themselves of [Defendant's] offer to make [] repairs."); *see also Midwest Printing*, 108 F.3d at 171; *Palmucci v. Brunswick*, 710 A.2d 1045, 1047-48 (N.J. Super. Ct. App. Div. 1998). The absence of such allegations here is fatal to the failure of essential purpose argument.

Second, even if Plaintiffs had alleged they registered for the repair/replacement program,

[12] Plaintiffs' warranty claims also fail because there is no allegation in the PIAC that any defect manifested in any particular plaintiff's device, let alone that it manifested within the two-year limited warranty period and that Respironics was timely notified of any such issue. MTD at 20 n.16. Plaintiffs' argument that the warranty period is "unconscionable" should be disregarded because they fail to allege any facts in the PIAC demonstrating procedural or substantive unconscionability. *See infra* Section VII.D.

[13] Plaintiffs' argument that the adequacy of their "failure of essential purpose" argument should not be resolved at this stage, Opp. at 23, is undermined by *Argabright v. Rheem Manufacturing Co*., 201 F. Supp. 3d 578, 594 (D.N.J. 2016), which dismissed a warranty claim where plaintiffs failed to "state[] a plausible claim that Defendants remedy failed of its essential purpose."

they also would need to allege facts sufficient to show that Respironics failed or refused to repair or replace their devices. *See BOC Grp., Inc. v. Chevron Chem. Co.*, 819 A.2d 431, 439 (N.J. Super. Ct. App. Div. 2003) ("A remedy may [] fail of its essential purpose if, after numerous attempts to repair, the product does not operate free of defects.") (citation omitted). The PIAC includes ***no*** allegations of any "refusal," repeated (unsuccessful) repairs, or "unreasonable delay" personal to any plaintiff sufficient to support a failure of essential purpose argument,[14] and the SFC does not require or invite individual plaintiffs to fill the gap with individualized facts.[15]

C. Certain Plaintiffs' Implied Warranty Claims Fail for Lack of Privity.

Plaintiffs assert that the seven jurisdictions Respironics identified as requiring direct vertical privity, MTD at 22, "embrace [] exceptions to [] privity requirements." Opp. at 24. To the extent these jurisdictions have recognized a third-party beneficiary exception (and cases Plaintiffs cite do not establish each has), Plaintiffs have alleged only bare legal conclusions, not facts sufficient to satisfy any such exception. *See* PIAC ¶ 496; RCT B(2).

D. Plaintiffs' Unconscionability Argument Fails.

Plaintiffs' argument that the two-year limit on Respironics' express and implied warranties[16] is "unconscionable" (Opp. at 24-25) should be rejected.[17]

First, contrary to Plaintiffs' argument (Opp. at 22 n.30), the existence of a competitive

[14] Plaintiffs cite generalized and conclusory allegations that Respironics' repair and replacement program has been "extremely slow," "inadequate," and "ineffective," *see, e.g.*, PIAC ¶¶ 291, 293 (referring to unidentified ***patients***, ***not Plaintiffs***), which are inadequate to support their argument.
[15] Plaintiffs' suggestion that a "bad faith exception" should prevent enforcement of a limited warranty here, Opp. at 23, is unavailing because Plaintiffs have failed to sufficiently allege bad faith conduct. *See infra* Sections X-XI.
[16] Plaintiffs do not dispute that "31 jurisdictions apply the durational limits in express warranties to related implied warranties." MTD at 21; CT A(2). Plaintiffs' cases do not say otherwise.
[17] Despite Plaintiffs' contention, Opp. at 24, whether they have sufficiently alleged unconscionability is appropriately considered on a motion to dismiss. *Alban v. BMW of N. Am., LLC*, No. 09-5398, 2011 WL 900114, at *1, *9 (D.N.J. Mar. 15, 2011).

product is relevant. The critical inquiry is whether there was "meaningful choice." *Vullings v. Bryant Heating and Cooling Sys*., No. 18-3317, 2019 WL 687881, at * 4 (E.D. Pa. Feb. 19, 2019). The PIAC alleges there was meaningful competition from ResMed, *see, e.g.*, PIAC ¶ 83, foreclosing a procedural unconscionability argument. *See, e.g.*, *In re Gen. Motors Air Conditioning Mktg. and Sales Pracs. Litig.*, 406 F. Supp. 3d 618, 628 (E.D. Mich. 2019) ("alternative sources of supply" and "options" weigh against procedural unconscionability).

Second, Plaintiffs' substantive unconscionability argument contends the limited warranty's duration was not "clear and conspicuous." *See* PIAC ¶ 505. But the Respironics limited warranties appended as Exhibits 47 and 48 to the PIAC reveal the duration terms are as prominent as the other warranty text. Plaintiffs' argument concerning the import of Respironics' alleged knowledge of the alleged defect is equally unavailing. *See Alban*, 2011 WL 900114, at *1, 9 (BMW's alleged knowledge of defect insufficient for finding durational limit unconscionable).

E. Pennsylvania Bars Implied Warranty Claims for Prescription Devices.

Plaintiffs do not dispute that the Pennsylvania Supreme Court has barred implied warranty claims concerning prescription drugs, but argue it has not expressly extended that bar to cover medical devices. Opp. at 25. This Court has predicted the Pennsylvania Supreme Court would extend the bar to cover medical devices and dismissed such claims in other cases, and the law has not changed since then. *See Killen v. Stryker Spine*, No. CIV.A. 11-1508, 2012 WL 4498865, at *4 (W.D. Pa. Sep. 28, 2012) (Conti, J.) (in medical device case, holding that implied warranty claim "based on failure to warn or design defect" was not cognizable under Pennsylvania law); *Kline v. Zimmer Holdings, Inc.*, No. CIV.A. 13-513, 2013 WL 3279797, at *6-7 (W.D. Pa. Jun. 27, 2013) (Conti, J.); *see also* MTD Section VI.E. Here, too, dismissal is the proper result.

F. Plaintiffs' Arguments Concerning Pre-Suit Notice Fail.

Plaintiffs argue that state law pre-suit notice requirements "do not apply in federal court,"

Opp. at 25, but a majority of courts in the Third Circuit disagree. *See In re Lipitor Antitrust Litig.*, 336 F. Supp. 3d 395, 416 (D.N.J. 2018) (collecting cases). Plaintiffs further argue that "the sufficiency of notice" "should not be decided on a Rule 12(b)(6) motion," Opp. at 25, yet fail to articulate why fact development is needed here. The only two notice letters the PIAC incorporates ***post-date*** commencement of this litigation and thus do not constitute valid notice. *See* RCT B(3). Nor does any "exception" to pre-suit notice requirements apply. *See* Opp. at 25 n.31; RCT B(4).

VIII. PLAINTIFFS' STRICT LIABILITY CLAIMS MUST BE DISMISSED FOR ADDITIONAL REASONS.

A. Strict Liability Design Defect Claims Are Unavailable in Certain States.

Respironics demonstrated in the MTD that Plaintiffs' strict liability design defect claims must be dismissed in certain jurisdictions that have adopted the Restatement (Second) of Torts, § 402A, cmt. *k* ("comment *k*").[18] Plaintiffs respond that application of comment *k* is "best left for determination on a more developed factual record," citing their Chart 6 which does not support that proposition (Opp. at 26), and in any event, discovery is irrelevant to this purely legal question. Waiting for a factual record will purchase only needless delay.

Plaintiffs further argue, erroneously and without support, that cases applying comment *k* to analogous medical products (drugs, vaccines, implanted medical devices) do not apply here. For example, *Yalter v. Endocare, Inc.*, No. SACV03 80, 2004 WL 5237598, at *4 (C.D. Cal. Nov. 8, 2004), *aff'd*, 220 F. App'x 657 (9th Cir. 2007) applied comment *k* to an implanted device but did not ***limit*** its holding to such devices. *Id.* at *4 ("The reason for this exception is that prescription drugs and medical devices are considered to be unavoidably unsafe products.").

Plaintiffs also argue this Court should ignore cases in certain jurisdictions that have

[18] Plaintiffs admit three other states do not allow any product liability claims based on strict liability. Respironics agrees that a District of Montana decision issued after this motion was filed declined to extend comment *k* to medical devices. Opp. at Chart 6.

extended comment *k* across-the-board to medical devices like the devices here in favor of cases from those same jurisdictions that have not. The cases extending comment *k* are better reasoned and should be followed on the same grounds underlying this Court's prior rulings that Respironics' position is correct under Pennsylvania law. *See Kline*, 2013 WL 3279797, at *1; *Killen*, 2012 WL 4498865, at *3-4. Plaintiffs' argument that this Court should not follow its own prior holdings reads too much into ancillary points in *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014) and *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), neither of which involved medical devices and both of which ignore the weight of authority following *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996) and its progeny, *Creazzo v. Medtronic, Inc.*, 903 A.2d 24 (Pa. Super. Ct. 2006). This Court is bound to proceed conservatively when interpreting contested issues of state law and Plaintiffs offer no sound basis for this Court to contradict its own prior reasoning or to defer ruling on this issue.

B. Plaintiffs' Strict Liability Manufacturing Defect Claim Must Be Dismissed.

Plaintiffs do not contradict the basic premise of Respironics' motion to dismiss with respect to their strict liability manufacturing defect claim—that the claim is premised on allegedly faulty manufacturing of a medical device, the Trilogy Evo Ventilator, that is not a part of this MDL. MTD at 27-28; Opp. at 28-29; *see also* JPML Transfer Order, ECF No. 203 at 2 n.4. Instead, Plaintiffs argue the Court should deny the motion because "this Court has the authority to determine the scope of this MDL through the CTO Process." Opp. at 29. But the CTO process is a process of the JPML, not the transferee court. *See* JPML Rule 7.1.[19] The PIAC alleges no actual "Recalled Device" with a manufacturing defect so this strict liability claim must be dismissed.

[19] Thus, *In re Exactech Polyethylene Orthopedic Prod. Liab. Litig.*, MDL No. 3044, 2022 WL 5408779 (J.P.M.L., Oct. 7, 2022), cited by Plaintiffs, is inapposite, as is *In re Hill's Pet Nutrition, Inc., Dog Food Prod. Liab. Litig.*, No. 19-CV-2672, 2020 WL 996802, at *9 (D. Kan. Mar. 2, 2020), in which both defendants and plaintiffs' co-lead counsel supported consolidation into the MDL of two cases filed directly in the MDL's district. No such situation exits here.

IX. PLAINTIFFS' NEGLIGENT MANUFACTURING CLAIM FAILS.

The PIAC alleges that the "Recalled Devices are ***defective in manufacture because*** the PE-PUR foam comprising part of the devices is subject to degradation and off-gassing and the PE-PUR foam contains toxic and carcinogenic materials." PIAC ¶ 475 (emphasis added). As explained in Respironics' MTD at 28-29, this allegation could describe only a ***design*** defect because the selection of an allegedly improper component is a failure of *design*.[20] Plaintiffs' attempt to recast their claim as a manufacturing defect fails because they do not allege that if Respironics had manufactured the devices differently they would not be defective. Nor do they allege that the products failed to meet manufacturing specifications. Since the manufacturing process is irrelevant, their claim must be for a design defect. "It is one thing to set forth theories in a brief; it is quite another to make proper allegations in a complaint." *Hughes v. United Parcel Serv., Inc.*, 639 F. App'x 99, 104 (3d Cir. 2016).

X. PLAINTIFFS' FRAUD AND NEGLIGENT MISREPRESENTATION CLAIMS MUST BE DISMISSED FOR ADDITIONAL REASONS.

Respironics' MTD demonstrated Plaintiffs' failure to plead with the specificity required by Rule 9(b): (i) any actionable conduct; (ii) causation; (iii) a duty to disclose under the laws of certain states; and (iv) valid negligent misrepresentation claims under the laws of eight states. Plaintiffs' Opposition does not remedy these pleading failures.

A. Plaintiffs Plead No Actionable Omission.

First, Plaintiffs correctly acknowledge their fraud and negligent misrepresentation claims are limited to omissions (not misrepresentations). However, they incorrectly argue that Rule 9(b)'s heightened pleading standard is "relaxed" for omission-based claims and that Rule 9(b) does not

[20] Disputing this, Plaintiffs cite two inapposite cases concerning implantation of a hip replacement after the FDA warned the manufacturer of a defective manufacturing process. *Bausch v. Stryker Corp.*, 630 F.3d 546, 549 (7th Cir. 2010); *Bass v. Stryker Corp.*, 669 F.3d 501, 510 (5th Cir. 2012).

apply to negligent misrepresentation claims. Opp. at 31. In *Bell*, 2018 WL 928237, at *5-6, this Court dismissed omission-based fraud claims under Rule 9(b) and made no mention of a relaxed standard. *See also* MTD at 29-30. Plaintiffs also ignore *Webb v. Volvo Cars of N.A., LLC*, No. Civ. 13-2394, 2018 WL 1470470, at *5 (E.D. Pa. Mar. 26, 2018), which applied Rule 9(b) to negligent misrepresentation claims in a similar product defect case. They instead cite *Sims v. Viacom, Inc*., Civ. A. No. 09-3521, 2009 WL 3856667, at *2 (E.D. Pa. Nov. 17, 2009), an inapposite case concerning an entertainment contract dispute. The Court should follow *Webb*.

Plaintiffs also mistakenly rely on *Majdipour v. Jaguar Land Rover N.A., LLC*, Civ. No. 12-cv-07849, 2013 WL 5574626 (D.N.J. Oct. 9, 2013), which highlights the PIAC's deficiencies by way of contrast. Opp. at 31. In *Majdipour*, the complaint alleged: (1) the specific marketing materials each plaintiff considered before purchasing their vehicle; (2) the specific representation made false by the defendant's purported omission upon which each plaintiff relied; and (3) the defendant employee with whom they interacted. *See* 2013 WL 5574626, at *1-2, 15. The PIAC alleges no similar detail, and the Master SFC neither requires nor invites individualized allegations similar to those in *Majdipour*.[21] Plaintiffs' argument that dismissal should wait until the bellwether process is unpersuasive, because individual plaintiffs must first allege viable claims before they should even be considered as candidates for bellwether proceedings.

Second, Plaintiffs have not pled facts demonstrating causation because they have not alleged they would have been aware of the purportedly omitted information. Plaintiffs' assertion, made for the first time in their Opposition (at 31-32), that "had [Respironics] disclosed the defect

[21] *In re Takata Airbag Product Liability Litigation*, 464 F. Supp. 3d 1291 (S.D. Fla. 2020), is similarly unhelpful to Plaintiffs because (1) it applied Eleventh Circuit law and (2) plaintiffs pled the sort of details about the purportedly false or misleading statements lacking in the PIAC. *Id.* at 1303-04.

to healthcare providers, the providers would have relayed the information to the Plaintiffs (and mostly likely, never have prescribed the Devices in the first instance)," must be disregarded on a motion to dismiss. *See Johnson v. Rite Aid (Derek Faight)*, No. Civ. A. No. 17-862, 2018 WL 4838540, at *14 (W.D. Pa. Oct. 4, 2018) (Conti, J.) ("[T]he court does not consider after-the-fact factual allegations because the focus of a motion to dismiss is upon the sufficiency of the complaint . . . . Plaintiff must plead all the factual allegations . . . within the complaint itself.").

The only case Plaintiffs cite in support of that argument, *McNeil v. Wyeth*, 462 F.3d 364, 373 (5th Cir. 2006), is inapposite because it concerned personal injury claims under a failure to warn theory—***not*** common law fraud—and its statement on failure to warn has been rejected. *See, e.g.*, *Gutierrez v. Ethicon, Inc.*, 535 F. Supp. 3d 608, 631-32 (W.D. Tex. 2021) ("[The Fifth Circuit's *McNeil* decision is not an accurate statement of Texas law . . . [as it] conflicts with the Supreme Court of Texas's more recent treatment of the learned intermediary doctrine.").

Third, Plaintiffs argue a duty to disclose may exist even absent a confidential or fiduciary relationship where: (1) a party has superior knowledge; (2) the defect goes to health and safety; or (3) the defendant made a partial disclosure but withheld material information. Opp. at 32. The first two alleged exceptions are not supported by the case law they cite. *See* RCT C(1). The third alleged exception likewise is inapplicable because the PIAC does not identify any Respironics statement, ***anywhere or to anyone***, rendered false or misleading by the purported omission, let alone one relied upon by any Plaintiff.

The quotes from marketing materials included in Paragraph 235 of the PIAC are no help to Plaintiffs. Opp. at 32. None is made false or misleading by a purported omission, and all are of a type deemed mere puffery by courts. *Compare* PIAC ¶ 235 (alleging Respironics "held itself out as a trusted brand," and a "global leader," whose products would help consumers "breathe

easier, sleep more naturally," and who offered "clinically proven" treatments)[22] *with Johnson v. Draeger Safety Diag., Inc*., 594 F. App'x 760, 766-67 (3d Cir. 2014) (affirming dismissal for failure to plead falsity); *Fusco v. Uber Tech., Inc.*, Civ. A. No. 17-00036, 2018 WL 3618232, at *6-7 (E.D. Pa. Jul. 27, 2018) (holding statements touting service as "safe" and "reliable" and that "you can trust" were puffery); *accord Castrol, Inc. v. Pennzoil Co*., 987 F.2d 939, 945 (3d Cir. 1993) ("[S]ales talk, or puffing . . . [is] understood as an expression of the seller's opinion only").

B. The Negligent Misrepresentation Claims Fail for Additional Reasons.

Plaintiffs oppose Respironics' showing that their negligent misrepresentation claims fail under eight states' laws, but cite no state-specific case law on point, as explained at RCT C(2).

XI. PLAINTIFFS' STATE CONSUMER PROTECTION CLAIMS ARE FORECLOSED BY STATUTES AND INSUFFICIENTLY PLED.

Respironics has set out multiple reasons why dismissal of Plaintiffs' 65 consumer protection law claims is required, supported by scores of authorities and principally grounded in Plaintiffs' assertion of claims that are foreclosed by the plain text of the consumer protection statutes that Plaintiffs invoke. MTD at 32-36. In response, Plaintiffs deride Respironics' arguments as "cursory," Opp. at 33, but fail to rebut the conclusion that dismissal is required.[23]

A. Plaintiffs Fail to Plead Viable Consumer Protection Claims.

Plaintiffs allege dozens of consumer protection claims that are expressly foreclosed by state

[22] Nor is there any allegation in the PIAC that the devices did not help consumers breathe easier or sleep more naturally, or were not a clinically proven treatment.

[23] Plaintiffs specifically fail to rebut that "bare citation of a statute does not suffice to allege the elements needed to state a plausible claim for relief under 65 different consumer protection laws." MTD at 32; *see Rector v. Toyota Motor Credit Corp.*, No. 13-CV-0400, 2013 WL 2151654, at *3 (E.D. Cal. May 16, 2013), (dismissing claims where "plaintiff's amended pleading offers only bare citations to federal statutes, and . . . plaintiff has not alleged facts sufficient to support those claims"), *report & recommendation adopted*, 2013 WL 12191879 (E.D. Cal. July 15, 2013).

laws they seek to invoke.[24] This failure is emblematic of their scattershot approach and compels dismissal of the claims, for the following principal reasons:

First, 14 states do not allow recovery for personal injury claims under at least one of their respective consumer protection statutes. MTD at 35 & CT F(4). Plaintiffs concede this point for 11 states but errantly argue that "the law is less clear than Philips asserts" in New Mexico, Ohio, and South Carolina. *See* Opp. at 35 & Chart 12; *see also, e.g.*, *Pena v. Scrip, Inc.*, No. CV 11-1102, 2013 WL 12334164, at *7 (D.N.M. Mar. 22, 2013) ("The weight of authority indicates that personal injury damages are not available under the UPA."); RCT D(1).

Second, five consumer protection statutes do not allow money damages for private rights of action. CT F(5). Plaintiffs offer no authority in opposition. Instead, they argue they seek injunctive and/or equitable relief under the consumer protection statutes. Opp. at 35 (citing PIAC ¶ 624).[25] Plaintiffs do not specify any relief they seek other than monetary damages, and the PIAC prayer for relief makes plain that Plaintiffs are seeking money damages. *See* PIAC at 107-08.[26] Even if Plaintiffs actually sought injunctive relief, they still fail to allege the absence of an adequate remedy at law. *Majesko v. Nationwide Mut. Ins. Co.*, No. 16-cv-222, 2017 WL 3499870, at *7 (N.D. Ga. Jan. 24, 2017) (dismissing UTPA injunctive relief claim for this reason).

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[24] Plaintiffs cite this Court's statement that the UTPCPL is a "uniform law" with similar provisions to other jurisdictions. Opp. at 33. This may be a fair generalization, but Plaintiffs fail to acknowledge there are also material differences in these statutes. What they seek here is for this Court to disregard those differences and their failure to account for those differences in the PIAC.

[25] PIAC ¶ 624 states in its entirety: "Plaintiffs demand judgment against Philips and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just."

[26] Plaintiffs assert Respironics is mistaken about Delaware's foreclosure of DTPA damages. Opp. at Chart 13. However, access to damages under the DPTA requires "a "claim for injunctive relief []supported by the allegations of facts that create a reasonable apprehension of a future wrong." *Tygon Peak Cap. Mgmt., LLC v. Mobile Invs. Investco, LLC*, No. CV 2019-0847, 2022 WL 34688, at *28 (Del. Ch. Jan. 4, 2022). Plaintiffs do not allege a future wrong.

Third, the devices are outside the scope of the consumer protection statutes in 24 jurisdictions because they are not "consumer" goods for "personal, family, or household use." MTD at 35 & CT F(7). Plaintiffs argue without support that the prescription medical devices at issue here are consumer goods because they are not surgically implanted prescription medical devices. Opp. at 35-36. Their inability to cite any authority recognizing this proposed distinction is for good reason—there is no logical or legal basis for it. Governing authority clearly holds that under consumer protection laws, as under the MMWA, prescription medical devices—whether implanted or non-implanted—are not "consumer goods." *See, e.g.*, *Collins v. Davol, Inc.*, 56 F. Supp. 3d 1222, 1231 n.9 (N.D. Ala. 2014); *Otis-Wisher v. Medtronic, Inc*., 616 F. App'x 433, 435 (2d Cir. 2015) (affirming consumer protection claim could not be stated because medical device "is not available for consumer purchase, but rather was prescribed"); *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 798 & n.2 (N.D. Ohio 2012) ("[P]rescription medical device [a non-implanted jet injector device] is not a good for personal, family or household use and thus is not a consumer good as defined by the OCSPA.").[27]

Fourth, in multiple jurisdictions, the private right of action for consumer protection claims is afforded only to direct purchasers or where there is privity. CT F(6). Plaintiffs disagree, Opp. at 35, but their arguments disregard both statutory language and governing case law. *See, e.g.*, *Anderson v. Merck & Co.*, 417 F. Supp. 2d 842, 848 (E.D. Ky. 2006) (Kentucky CPA claim requires privity); *In re Insulin Pricing Litig*., No. 317CV699, 2020 WL 831552, at *5, 9 (D.N.J.

[27] In line with their specious distinction between implanted and non-implanted medical devices, Plaintiffs dubiously cite consumer protection cases concerning drugs and homeopathic products for the unsustainable premise that prescription medical devices should also come within the scope of those same consumer protection claims. Neither settlement agreements, non-private right of action cases nor other prescription medication cases can or do sustain the notion that medical devices qualify as a consumer good under state consumer protection law. *See* RCT D(2).

Feb. 20, 2020) (dismissing Arizona and Washington claims brought by indirect purchasers).

Fifth, the consumer protection claims are preempted as a matter of federal law, *see supra* Section III, and expressly exempted under consumer protection laws of 12 states. MTD at 33 & CT F(1). Plaintiffs contend statutory exemptions apply only "when conduct being challenged has been specifically approved by a regulatory agency." Opp. at 34. However, *State v. Piedmont Funding Corp.* rejects this view as "the Legislature clearly exempted from the Act all those activities and businesses which are subject to monitoring by state or federal regulatory bodies or officers." 382 A.2d 819, 822 (R.I. 1978). Rather than exempting only matters approved by a regulatory agency, *Adkins v. Collens* holds the Alaska UTPA exemption applies to "acts or transactions" which are ***prohibited*** and "the subject of 'ongoing careful regulation." 444 P.3d 187, 195 (Alaska 2019).

Sixth, in five jurisdictions, the consumer protection claims are subsumed by state product liability acts. CT B(2). Plaintiffs concede this is true of Louisiana, but dispute Indiana, and argue that subsumption "is subject to analysis by the Court" in the other three jurisdictions. Opp. at 36 & n.43. Now is the correct time for such analysis. The Court should find that PLAs five jurisdictions subsume consumer protection claims when based entirely on personal injury and the PIAC exclusively asserts personal injury claims. *See* RCT A(1).

Seventh, Plaintiffs concede the existence of pre-suit notice requirements in 11 jurisdictions, *see* MTD at 36, but argue their non-compliance with the statutes should be excused. Opp. at 36-37. A compliant pre-suit demand letter is a ***condition precedent*** to stating a claim in those states. Plaintiffs argue they have sufficiently alleged compliance, Opp. at 36, and cite four paragraphs of the PIAC. Three are identical and found in other causes of action (¶¶ 506, 529, 558). The fourth, found in the consumer protection claims, states, in full: "Philips is on notice that such claims may

be asserted by those Plaintiffs." *Id.* ¶ 608.[28] This conclusory allegation is insufficient given the absence of either pre-suit or compliant notice.[29]

B. Plaintiffs Have Not Pled with Particularity as Required by Rule 9(b), and Have Insufficiently Pled Causation, Reliance, Scienter, and In-State Activity.

Plaintiffs acknowledge that fraud claims must be pled pursuant to Rule 9(b), but contend that Rule 9(b)'s particularity requirement does not apply to some of their state consumer protection claims because not "all state consumer protection claims sound in fraud." Opp. at 31, 34. As the PIAC makes plain, every single one of Plaintiffs' consumer protection claims sounds in fraud. *See, e.g.*, PIAC ¶ 606 ("Certain Plaintiffs herein will bring a cause of action for consumer fraud and/or unfair and deceptive trade practices under applicable state law."). If a consumer protection claim rests on allegations of deceptive conduct, as is the case here, *see, e.g.*, *id.* ¶¶ 611-13, Rule 9(b) applies, and Plaintiffs "must plead with particularity the circumstances constituting fraud." *Benson v. Fannie May Confections Brands, Inc.*, 944 F.3d 639, 646 (7th Cir. 2019); *see also Bogart v. Glenmark Generics, Inc., USA*, No. 14-CV-778, 2014 WL 5800577, at *4 (S.D. Cal. Nov. 7, 2014) ("Ninth Circuit has held that under California law, CLRA claims of misrepresentation are grounded in fraud even if fraud is not actually alleged.").[30] As shown above, *supra* Section X,

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[28] Plaintiffs argue that Philips improperly attaches some, but not all, of the notices that it received from Plaintiffs. Opp. at 36. Respironics properly attached to its MTD the notices that Plaintiffs elected to incorporate by reference in the PIAC, and no others. *See* MTD at 24 n.23.

[29] *See, e.g.*, *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 350 F. Supp. 2d 160, 183 (D. Me. 2004) (dismissing Georgia FBPA claim for failure to provide statutory pre-suit notice). Although dismissal is generally the rule where proper pre-suit notice is not provided, *In re Ranbaxy Generic Drug Application Antitrust Litigation*, No. 19-md-02878, 2020 WL 2308839, at *3 (D. Mass. May 8, 2020), cited by Plaintiffs, allowed the Maine UTPA claim to proceed despite lack of pre-suit notice because consequences other than dismissal may be appropriate, such as denying an award of attorneys' fees; however, the court dismissed the WVCCPA claim with prejudice.

[30] Plaintiffs rely on a single jurisdiction to argue that a heightened pleading standard does not apply to all consumer protection claims. Opp. at 34. But *Pleasant v. McDaniel*, 550 S.W.3d 8, 12 (Ark.

Plaintiffs fail to plead their claims with the necessary particularity.

The PIAC also fails to sufficiently plead causation (required in 37 jurisdictions), reliance (required in at least 29 jurisdictions), and scienter (required in at least 14 jurisdictions).[31] In arguing they sufficiently pled causation and reliance, Plaintiffs simply point to every paragraph of Count XVI and five additional conclusory paragraphs (four of which are nearly identical), but none of these paragraphs allege specific facts supporting causation or even assert reliance on the part of Plaintiffs. Opp. at 34 (citing PIAC ¶¶ 605-24, 25, 566, 583, 611, 627). Once "plaintiffs' recitation of formulaic elements of the claims" are omitted and "legal arguments" disregarded, there is nothing left beyond a facially deficient pleading. *Tatel v. Mt. Lebanon Sch. Dist.*, No. CV 22-837, 2022 WL 15523185, at *7 (W.D. Pa. Oct. 27, 2022) (Conti, J.). Likewise, in arguing that they sufficiently pled scienter, Plaintiffs cite a large swath of the PIAC, Opp. at 34 (citing PIAC ¶¶ 166-234, 248-50), hoping that the heft of their citation will overcome the paucity of relevant allegations.

Twenty states and the District of Columbia require that the conduct at issue occurred within the state and, in some cases, primarily and substantially within the state. MTD at 36 & CT F(8). Arguing that Respironics "simply ignores specific allegations about the business conducted in each

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Ct. App. 2018), cited by Plaintiffs, is an outlier. The "heightened pleading standard of Rule 9(b) applies to Plaintiffs' ADTPA claims." *Edwards v. Camden Operations, LLC*, No. 17-CV-01054, 2018 WL 3478905, at *2 (W.D. Ark. Jul. 19, 2018); *Green v. Skyline Highland Holdings LLC*, No. 17-CV-00534, 2018 WL 3800240, at *2 (E.D. Ark. Jun. 12, 2018) (same).

[31] Plaintiffs concede reliance must be pled in 29 jurisdictions, *see* Opp. at Chart 10, and do not challenge that causation must be pled in 37 jurisdictions. *See id.* at 34. Plaintiffs are mistaken as to the requirement of pleading reliance under Maryland law. *Richards v. New Rez, LLC*, No. 20-1282, 2022 WL 657568, at *29 (D. Md. Mar. 4, 2022) (allegations of causation and reliance required); *see also* RCT D(3). Further, Plaintiffs concede scienter must be pled under the statutes of 13 jurisdictions. *See* Opp. at Chart 11. They are mistaken as to Illinois law. *Hart v. Amazon.com, Inc*., 191 F. Supp. 3d 809, 822 (N.D. Ill. 2016) (scienter must be alleged), *aff'd*, 845 F.3d 802 (7th Cir. 2017)*; see* RCT D(4).

jurisdiction," Plaintiffs cite a single conclusory PIAC paragraph. Opp. at 36 (citing PIAC ¶ 610).[32] While Plaintiffs may wish to blithely disregard the specific requirements of the state statutes they seek to invoke, it is not something they can properly ask this Court to do. *See Cont'l Res., Inc. v. Wolla Oilfield Servs. LLC*, No. 20-CV-00200, 2021 WL 2905412, at *4 (W.D. Okla. Jul. 9, 2021) ("The mere fact that a transaction has a material impact on or nexus to a consumer in Oklahoma, without more, is not enough to invoke this state's consumer protection laws. The focus is on the location of the offending conduct, and such conduct must occur in this state.").

XII. PLAINTIFFS' UNJUST ENRICHMENT CLAIM FAILS.

Respironics demonstrated there is no claim for "unjust enrichment" in the personal injury context. MTD at 37. Plaintiffs argue they "conferred a benefit on Philips by ***using*** Devices that were purchased or leased on their behalf." Opp. at 37 (emphasis added). But that does not address Respironics' core argument and, in any event, Plaintiffs' alleged "use" of the recalled devices certainly confers no financial benefit on Respironics. Indeed, Plaintiffs' own caselaw holds that unjust enrichment is unavailable precisely because plaintiffs received and used the product. *Bostic v. Ethicon, Inc.*, No. 20-6533, 2022 WL 952129 at *16 (E.D. Pa. Mar. 29, 2022) ("[i]n products liability cases, courts in this Circuit applying Pennsylvania law dismiss unjust enrichment claims where the plaintiff received and used the product at issue.") (citation omitted).[33]

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[32] PIAC ¶ 610 alleges: "Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in each jurisdiction. In addition, in those jurisdictions, Philips sold the Recalled Devices, shipped Recalled Devices, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices." Plaintiffs also contend that there are "other allegations about the scope of Philips' business," Opp. at 36, but do not identify these additional allegations or even explain how these allegations might support the raft of conclusions asserted without factual support in PIAC ¶ 610.

[33] Assuming *arguendo* unjust enrichment could be framed as an economic injury cause of action, Respironics has already demonstrated that Plaintiffs' claim fails, for all the reasons set forth in the Respironics' Mem. in Support of Motion to Dismiss the TAC at 32-34 (ECF No. 916) and Respironics' Reply Mem. in Support of Motion to Dismiss the TAC at 17-18 (ECF No. 1728).

XIII. PLAINTIFFS' BATTERY CLAIM MUST BE DISMISSED.

Plaintiffs' failure to plead facts plausibly demonstrating intent is fatal to their battery claim. They argue, erroneously, that their allegations that (i) Respironics knew of and concealed the alleged defects, and (ii) Respironics' continued sales of the devices "result[ed] in harm to the Plaintiffs," are sufficient to "support[] a claim for battery." Opp. at 38. These allegations do not describe intentional conduct.

Plaintiffs do not even attempt to argue they alleged Respironics acted "for the purpose of bringing about a harmful or offensive contact." Restatement (Second) of Torts, § 18 cmt. *e*. They argue that under the "substantial certainty" prong of the Restatement they "need only allege [Respironics] intended to take action that it knew was likely to result in harmful or offensive contact." Opp. at 38. The cases Plaintiffs cite demonstrate that to properly allege intent under the substantial certainty prong, a plaintiff still must allege the defendant ***intended to cause the contact*** that was substantially certain to lead to harm.[34]

The PIAC is devoid of any such allegations, much less allegations that Respironics intended contact with Plaintiffs to be harmful and offensive. Plaintiffs have failed to allege intent, mandating dismissal of their battery claim.

XIV. NEGLIGENCE PER SE NOT A SEPARATE CAUSE OF ACTION IN 27 STATES.

In the MTD, Respironics identified 27 states that do not recognize negligence *per se* as an independent cause of action. CT G(1). Plaintiffs do not dispute the law of those states. Instead,

[34] *Field v. Philadelphia Electric Co.*, 565 A.2d 1170, 1178 (Pa. Super Ct. 1989), involved radiation exposure at a nuclear plant where plaintiff alleged facts suggesting his employer "deliberately exposed [him] to radiation . . . by deliberately venting radioactive steam on [him] knowing his location." *Adams v. Dole Food Co.*, 323 P.3d 122, 136 (Haw. Ct. App. 2014), involved allegations defendant "intentionally exposed [plaintiff-employees]" to a chemical pesticide. *Johnson v. Sunoco, Inc. (R&M)*, No. CV 05512, 2018 WL 925009 (E.D. Pa. Feb. 15, 2018)—the sole case involving a product placed into the stream of commerce—involved claims defendants directly "intended to cause harmful contact to [Plaintiff] by causing benzene exposure." *Id.* at *2.

they argue that in those states, negligence *per se* is "integrate[d]" into a general negligence claim, that Respironics' challenge to their negligence *per se* claim is "unnecessary and premature," and entreat the Court to delay addressing the issue until the bellwether process. Opp. at 39. But dismissal of non-cognizable negligence *per se* claims is entirely proper on a motion to dismiss under Fed.R.Civ.P. 12(b)(6). *See, e.g.*, *In re Valsartan*, 2021 WL 364663, at *22 (granting with prejudice motion to dismiss stand-alone negligence *per se* claims arising under state laws that do not recognize such a claim).

XV. PUNITIVE DAMAGES ARE NOT A CAUSE OF ACTION.

Plaintiffs do not dispute this Court's ruling that a "request for punitive damages does not constitute a cause of action in [and] of itself. . . . [It] is merely incidental to a cause of action." *N. Side Foods Corp. v. Bag-Pack, Inc.*, No. CIV.A. 06-1612, 2007 WL 954106, at *3 (W.D. Pa. Mar. 28, 2007) (Conti, J.) (citation omitted). Instead, Plaintiffs fall back on their familiar plea for needless delay. Plaintiffs note this Court did not dismiss a request for punitive damages in *North Side Foods*, but omit that the plaintiff in that case did not assert punitive damages as an independent cause of action. Punitive damages as a ***remedy*** may be determined later, but Plaintiffs do not even try to justify the assertion of punitive damages as a standalone count. Count XXI should be dismissed.[35]

CONCLUSION

For all the foregoing reasons, and those stated in Respironics' Motion, the PIAC should be dismissed in its entirety and with prejudice.

[35] Plaintiffs' Opposition includes no substantive response to Respironics' position challenging the PIAC's medical monitoring claims. Plaintiffs lead with yet another request for delay, then refer to their Opposition to Respironics' MTD the MMSAC. For the same reasons, Respironics respectfully refers the Court to the Reply Mem. in Support of Respironics' Motion to Dismiss the MMSAC (filed on this date contemporaneously herewith), for points specifically relating to medical monitoring.

Dated: April 21, 2023

Respectfully Submitted,

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REPLY CITATION TABLES

CITATION TABLE A – SUBSUMPTION

A(1) Respironics' Response to Cases Cited in Plaintiffs' Chart 2.

Connecticut: *Gerrity v. R.J. Reynolds Tobacco Co.*, 818 A.2d 769, 775-776 (Conn. 2003) (financial injury claims not subsumed). **Respironics' response**: Plaintiffs do not claim financial injury in the PIAC.

Indiana: *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, MDL No. 2875, 2021 WL 364663, at *13 (D.N.J. Feb. 3, 2021) (express and implied warranty, and consumer protection claims not subsumed). **Respironics' response:** *Palm v. Taurus Int'l Mfg., Inc.*, No. 22-cv-337, 2022 WL 17714600, at *4 (N.D. Ind. Dec. 15, 2022) holds that breach of warranty arising from claims of pure personal injury are subsumed. *Elward v. Electrolux Home Prods., Inc.*, 264 F. Supp. 3d 877, 891-92 (N.D. Ill. 2017) (applying Indiana law) holds that IDCSA claims are subsumed where, as here, they are based purely on physical harm.

Kansas: *Mattos v. Eli Lilly & Co.*, No. 12-1014, 2012 WL 1893551, at *2-3 (D. Kan. May 23, 2012) (KCPA claims not subsumed). **Respironics' response:** We do not argue KCPA claims are subsumed.

Louisiana: *Stroderd v. Yamaha Motor Corp., U.S.A.*, No. 04-3040, 2005 WL 2037419, at *2 (E.D. La. Aug. 4, 2005) (redhibition claims not subsumed). **Respironics' response:** Redhibition is not available for personal injury claims. *Fussell v. Johnson & Johnson,* No. CV 20-3474, 2021 WL 5907702, at *4 (E.D. La. Dec. 14, 2021) ("Any non-LPLA claim based on non-economic losses, including redhibition, must be dismissed.").

Mississippi: *Knoth v. Apollo Endosurgery US, Inc.*, 425 F. Supp. 3d 678, 687 (S.D. Miss. 2022) (common law theories are not unavailable). **Respironics' response:** Common law theories are available only through the MPLA. *Knoth* held that "where a common law claim is subsumed by the MPLA, . . . the proper course is to dismiss the common law claim to the extent it is duplicative . . . . To the extent a subsumed common law claim is asserted as an independent tort claim outside the scope of the MPLA, the count must be dismissed . . . ." *Id.* (internal quotation marks and citation omitted).

New Jersey: *Valsartan*, 2021 WL 364663 at *7 (CFA claims not subsumed). **Respironics' response:** *Valsartan* held CFA claims subsumed when brought entirely as personal injury claims, as here.

Ohio: *Hollar v. Philip Morris Inc.*, 43 F. Supp. 2d 794, 808 (N.D. Ohio 1998) (common law fraud claim not subsumed); *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 943 (S.D. Ohio 2010) (UCC warranty claim not subsumed). **Respironics' response:** *Hollar* held plaintiffs' common law fraud claim not subsumed because it went "beyond a products liability claim." Here, Plaintiffs bring a products liability claim based entirely on personal injury. To the extent Plaintiffs' breach of warranty claims arise under Ohio common law, they are subsumed. *See Miles v. Raymond Corp*., 612 F. Supp. 2d 913, 921-28 (N.D. Ohio 2009).

Tennessee: *Valsartan*, 2021 WL 364663, at *7 (TCPA claim not subsumed). **Respironics' response:** Respironics does not argue that TCPA claims are subsumed.

Washington: *Cutter v. Biomet, Inc.*, No. 18-cv-06033, 2019 WL 2450785, at *1 (W.D. Wash. Jun. 12, 2019) (common law fraud, intentional tort claims not subsumed). **Respironics' response:** We do not seek dismissal based on subsumption for fraud or intentional tort claims under Washington law.

CITATION TABLE B – WARRANTY

B(1) "Workmanship and Materials" Warranties Cover Only Manufacturing Defects.

Arizona, Illinois, Michigan, *and* New York: *Raynaldo v. Am. Honda Motor Co.*, No. 21-CV-05808, 2022 WL 4358096, at *12 (N.D. Cal. Sep. 20, 2022);

California, Maryland, *and* Tennessee: *Tait v. BSH Home Appliances Corp.*, No. SACV 10-711, 2011 WL 1832941, at *3 (C.D. Cal. May 12, 2011);

Colorado, Ohio, Texas, *and* Utah: *Rollolazo v. BMW of N. Am., LLC*, No. CV1600966, 2017 WL 6888501, at *9 (C.D. Cal. May 2, 2017);

Hawaii, South Dakota, *and* Wisconsin: *In re Ford Motor Co. F-150 & Ranger Truck Fuel Econ. Mktg. & Sales Litig.*, No. 19-MD-02901, 2022 WL 551221, at *21 (E.D. Mich. Feb. 23, 2022);

Kentucky, Nevada, South Carolina, *and* Virginia: *Flores v. FCA US LLC*, No. 20-10972, 2021 WL 1122216, at *9 (E.D. Mich. Mar. 24, 2021);

New Jersey: *Coba v. Ford Motor Co.*, 932 F.3d 114, 123 (3d Cir. 2019);

Oregon: *Martell v. Gen. Motors LLC*, 492 F. Supp. 3d 1131, 1141 (D. Or. 2020);

Pennsylvania: *Mack Trucks v. BorgWarner Turbo Sys., Inc.*, 508 F. App'x 180, 184-85 (3d Cir. 2012); ***and***

Alabama, Arkansas, Delaware, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Louisiana, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, New Mexico, North Carolina, North Dakota, Oklahoma, Washington, West Virginia, *and* Wyoming: *Sloan v. Gen. Motors LLC*, No. 16-CV-07244, 2017 WL 3283998, at *8 (N.D. Cal. Aug. 1, 2017).

B(2) In Jurisdictions That Recognize Exceptions to Direct Vertical Privity, Plaintiffs' Conclusory Allegations Are Insufficient to Invoke Them.

Arizona: *Naiman v. Alle Processing Corp.*, No. CV20-0963, 2020 WL 6869412, at *3 (D. Ariz. Nov. 23, 2020) (recognizing a public health exception for products of human consumption, e.g., pesticides and pharmaceuticals not at issue here); *Crystal Coca-Cola Bottling Co. v. Cathey*, 317 P. 2d 1094, 1097 (Ariz. 1957) (same);

Florida: *Weiss v. Gen. Motors LLC*, 418 F. Supp. 3d 1173, at 1182-83 (S.D. Fla. 2019) (acknowledging that plaintiff's complaint alleges that [1] GM does business in Florida through its authorized dealerships; and [2] plaintiff purchased a vehicle from one of those dealerships; and that [3] GM's warranties are intended for consumers of GM's vehicles); *see also Carder v. Graco Children's Prod., Inc.*, 558 F. Supp. 3d 1290, 1319 (N.D. Ga. 2021) (acknowledging that in Florida plaintiffs must plead details such as "when, how, and from whom their [products] were purchased" to satisfy third party beneficiary exception);

Georgia: *Lee v. Mylan Inc.*, 806 F. Supp. 2d 1320, 1325-26 (M.D. Ga. 2011) ("Georgia law still generally precludes the ultimate consumer from recovering on any express or implied warranty when the manufacturer sells the product to the original consumer, e.g. a retailer."); *Andrews v. RAM Med., Inc.*, No. 11-CV-147, 2012 WL 1358495, at *3 (M.D. Ga. Apr. 19, 2012);

CITATION TABLE B – WARRANTY

Idaho: *Am. W. Enters. v. CNH, LLC*, 316 P.3d 662, 668-69 (Idaho 2013) (acknowledging that the third party beneficiary test under Idaho law requires the third party to "show that the contract [between the manufacturer and retailer] was made primarily for his benefit . . . the contract itself must express an intent to benefit the third party");

Kentucky: *Levin v. Trex Co., Inc.*, No. 10-cv-692, 2012 WL 7832713, at *2 (W.D. Ky. March 5, 2012) (holding that "without a direct buyer-seller relationship, Plaintiff's claim for breach of an implied warranty against Defendant fails as a matter of law"); *see also In re ConAgra Peanut Butter Prod. Liab. Litig.*, No. 07-MD-1845, 2012 WL 3779088, at *2 (N.D. Ga. Aug. 29, 2012) (applying Kentucky law);

Oregon: *Compare Smith v. Ethicon Inc.*, No. 20-CV-00851, 2021 WL 3578681, at *8 (D. Or. May 13, 2021) (finding personal injury plaintiff established any necessary privity to state implied warranty claim) *with Simonsen v. Ford Motor Co*., 102 P.3d 710, 721 (Or. 2004) ("[A]s defendant contends, privity of contract is a necessary prerequisite in a breach of contract claim for personal injuries."); ***and***

Wisconsin: *Grams v. Milk Products, Inc.*, 685 N.W.2d 172, ¶ 12 (Wis. Ct. App. 2004) ("[T]here must be evidence, on the part of the promisee, that he intended to directly benefit a third party, and not simply that some incidental benefit was conferred on an unrelated party by the promisee's actions under the contract. There must be evidence that the promisee assumed a duty to the third party.") (citations omitted).

B(3) Notice That Post-Dates Commencement of Litigation is Legally Insufficient.

Lisowski v. Henry Thayer Co., No. CV 19-1339, 2021 WL 1185924, at *3 (W.D. Pa. Mar. 30, 2021); *Huskey v. Colgate-Palmolive*, No. 19-CV-0271, 2020 WL 6342704, at *2 (E.D. Mo. Oct. 27, 2020); *Johnston v. PhD Fitness, LLC*, No. 16-CV-14152, 2018 WL 646683, at *4 (E.D. Mich. Jan. 31, 2018); *Donohue v. Apple, Inc.*, 871 F. Supp. 2d 913, 928-29 (N.D. Cal. 2012).

B(4) No Exceptions to Pre-Suit Notice Requirements Apply.

Alabama: *Lindsey v. Int'l Shoe Co.*, 233 So.2d 507, 508-09 (Ala. Civ. App. 1970) (in personal injury case, notice of breach "must be affirmatively pleaded in the complaint");

Arkansas: *Jarrett v. Panasonic Corp. of N. Am.*, 8 F. Supp. 3d 1074, 1083 (E.D. Ark. 2013) (plaintiff sought to return product, unlike Plaintiffs here);

California: *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Pracs., & Prod. Liab. Litig.*, 754 F. Supp. 2d 1145, 1180 (C.D. Cal. 2010) (purchaser "did not deal" with manufacturer, unlike Plaintiffs here who allege they "dealt directly with Philips");

Colorado: *Gregorio v. Ford Motor Co.*, 522 F. Supp. 3d 264, 285 (E.D. Mich. 2021) (unlike here, warranty did not require written notice of defect);

Connecticut: *Leonard v. Gen. Motors L.L.C.*, 504 F. Supp. 3d 73, 99 (D. Conn. 2020) (notice of breach required to manufacturer in personal injury case);

Florida: *In re FCA US LLC Monostable Elec. Gearshift Litig.*, 446 F. Supp. 3d 218, 228 (E.D. Mich. 2020) (requiring pre-suit notice to manufacturer);

CITATION TABLE B – WARRANTY

Georgia: *Pulmonary Assocs. of Charleston PLLC v. Greenway Health, LLC*, 508 F. Supp. 3d 1268, 1275 (N.D. Ga. 2020) (unlike here, manufacturer had opportunity to cure defect);

Illinois: *In re Rust-Oleum Restore Mktg., Sales Pracs. & Prod. Liab. Litig.*, 155 F. Supp. 3d 772, 800 (N.D. Ill. 2016) (no actual knowledge of defect here);

Indiana: *Anderson v. Gulf Stream Coach, Inc.*, 662 F.3d 775, 782 (7th Cir. 2011) (same);

Iowa: *In re MyFord Touch Cons. Litig.*, 46 F. Supp. 3d 936, 974-77 (N.D. Cal. 2014) (no allegation that warranty's terms required notice to manufacturer, unlike warranty at issue here);

Maryland: *Doll v. Ford Motor Co.*, 814 F. Supp. 2d 526, 542 (D. Md. 2011) (requiring notice to "immediate seller," which Plaintiffs here do not allege);

Massachusetts: *In re Ford Motor Co. E-350 Van Prod. Liab. Litig. (No. II)*, No. CIV. A. 03-4558, 2010 WL 2813788, at *79 (D.N.J. Jul. 9, 2010) (unlike here, warranty did not require written notice of defect);

Michigan: *Johnston v. PhD Fitness, LLC*, No. 16-CV-14152, 2018 WL 646683, at *3 (E.D. Mich. Jan. 31, 2018) (filing suit does not constitute notice);

Minnesota: *Christian v. Sony Corp. of Am.*, 152 F. Supp. 2d 1184, 1188 (D. Minn. 2001) (knowledge of defect does not constitute notice);

Mississippi: *Albright v. Sherwin-Williams Co.*, No. 17 CV 2513, 2019 WL 5307068, at *3 (N.D. Ohio Jan. 29, 2019) (plaintiff complained about defect prior to filing suit, unlike Plaintiffs here);

New Jersey: *Kury v. Abbott Lab'ys, Inc.*, No. CIV.A. 11-803, 2012 WL 124026, at *7 (D.N.J. Jan. 17, 2012) ("pre-litigation notice of breach" required);

New Mexico: *Badilla v. Wal-Mart Stores E.*, 389 P.3d 1050, 1054 ("No New Mexico case holds that the filing or service of a complaint constitutes sufficiently timely notice of a warranty claim");

New York: *Clemmons v. Upfield US Inc.*, No. 22-CV-355, 2023 WL 2752454, at *9 (S.D.N.Y. Mar. 31, 2023) ("majority of courts" hold that filing suit does not constitute notice);

North Carolina: *Kacsuta v. Lenovo (United States) Inc.*, No. SACV1300316, 2013 WL 12126775, at *2 (C.D. Cal. Jul. 16, 2013) (filing suit does not constitute notice);

Ohio: *Forsher v. J.M. Smucker Co.*, No. 19CV00194, 2020 WL 1531160, at *8 (N.D. Ohio Mar. 31, 2020) (same);

Pennsylvania: *In re Shop-Vac Mktg. & Sales Pracs. Litig.*, 964 F. Supp. 2d 355, 364 (M.D. Pa. 2013) (same);

South Carolina: *Lessin v. Ford Motor Co.*, No. 19CV01082, 2021 WL 3810584, at *6 (S.D. Cal. Aug. 25, 2021) (notice satisfied where plaintiff presented product for repair, which no Plaintiff here alleges);

Tennessee: *Bunn v. Navistar, Inc.*, 797 F. App'x 247, 253 (6th Cir. 2020) (filing suit does not constitute notice);

Texas: *Del Castillo v. PMI Holdings N. Am.*, No. 14-CV-03435, 2016 WL 3745953, at *3 (S.D. Tex. Jul. 13, 2016) (holding the case Plaintiffs cite, *Vintage Homes*, "is no longer good law"); ***and***

Virginia: *Hammerschmidt v. Gen. Motors LLC*, 583 F. Supp. 3d 1215, 1224 (D. Minn. 2022), *appeal dismissed* (May 2, 2022) (applying Virginia law) (filing suit does not constitute notice).

CITATION TABLE C – FRAUD AND NEGLIGENT MISREPRESENTATION

C(1) Duty to Disclose Exceptions (select jurisdictions): Respironics' Response to Cases Cited in Plaintiffs' Chart 7.

Alabama: *Freightliner, L.L.C. v. Whatley Contract Carriers, L.L.C.*, 932 So.2d 883, 895 (Ala. 2005) (partial disclosure); *Hughes v. Hertz Corp.*, 670 So. 2d 882, 887-88 (Ala. 1995) (health and safety exception). **Respironics' response**: As to *Freightliner, see* Respironics' Reply Mem. in Support of Motion to Dismiss the PIAC ("Reply") at 17-18. As to *Hughes*, *see Garcia v. Chrysler Group LLC*, 127 F. Supp. 3d 212, 235 n.21 (S.D.N.Y. 2015) (holding *Hughes* inapplicable outside of the used car sale context).

Arkansas: *Holiday Inn Fran., Inc. v. Hotel Assocs., Inc*., 382 S.W.3d 6, 14 (Ark. Ct. App. 2011) (superior knowledge); *Zimpel v. Trawick*, 679 F. Supp. 1502, 1509 (W.D. Ark. 1988) (partial disclosure). **Respironics' response**: *Holiday Inn* involved an appeal from a jury verdict by a hotel franchisor who argued it had no duty to a franchisee to disclose the franchisor had decided four years into a ten-year licensure not to renew. 382 S.W.3d at 11. The court rejected that argument because the parties' "long-term relationship . . . characterized by honesty, trust, and the free flow of pertinent information" amounted to a special relationship that created a duty even in the absence of a formal fiduciary relationship. *Id*. at 12. Here, Respironics is a "remote manufacturer," *see*, *e.g*., PIAC ¶ 506, who consumer Plaintiffs did not deal with directly, or at most only dealt with "through the exchange of warranty and recall information," see, *e.g*., *id.* ¶ 497; as to *Zimpel, see* Reply at 17-18.

Connecticut: *Wedig v. Brinster*, 469 A.2d 783, 788 (Conn. App. 1983) (partial disclosure). **Respironics' response:** *See* Reply at 17-18.

Delaware: *Arcelik, A.S. v. E.I. Du Pont de Nemours & Co.,* Civ. A. No. 15-00961, 2022 WL 3139086, at *8 (D. Del. Aug. 5, 2022) (partial disclosure); Delaware Pattern Civil Jury Instructions § 16.3, DEL. P.J.I. CIV. § 16.3 (2000) (active concealment); *Rohm & Haas Elec. Materials, LLC v. Honeywell Int'l, Inc.,* C.A. No. 06-297, 2009 WL 1033651, at *7 (D. Del. Apr. 16, 2009) (partial disclosure). **Respironics' response:** As to *Arcelik* and *Rohm*, *see* Reply at 17-18. The civil jury instructions Plaintiffs cite merely note that a duty to disclose is one element of a fraudulent concealment claim under Delaware law. *See* DEL. P.J.I. CIV. § 16.3 (2000).

Florida: *Nessim v. DeLoache*, 384 So. 2d 1341, 1344 (Fla. App. 1980) (superior knowledge); *Nicholson v. Kellin*, 481 So. 2d 931, 936 (Fla. App. 1985) (partial disclosure); *S.K.Y. Mgmt. LLC v. Greenshoe, Ltd*., 2007 WL 9701121, at *3 (S.D. Fla. Mar. 11, 2007) (superior knowledge); *BVS Acquisition Co., LLC v. Brown*, 649 F. App'x 651, 665 (11th Cir. 2016). **Respironics' response:** As to *Nessim, see TransPetrol, Ltd. v. Radulovic*, 764 So.2d 878, 880 (Fla. Dist. Ct. App. 2000) (distinguishing *Nessim* because parties were in a direct buyer-seller relationship where seller misrepresented yacht was in good condition despite knowing it had latent defects). As to *Nicholson, see* Reply at 17-18. *S.K.Y.* did not hold superior knowledge alone is sufficient; it requires superior knowledge ***and*** affirmative acts of concealment by the defendant, including during direct interactions not alleged here. 2007 WL 9701121, at *3; *see also Solar Eclipse Inv. Fund VII, LLC v. T-Mobile USA, Inc.*, No. 20-24012 Civ, 2022 WL 6567110, at *8 (S.D. Fla. Sep. 2, 2022) (no duty to disclose where plaintiffs failed to plead any direct relationship with defendant), report and recommendation adopted in relevant part sub nom. *Luria v. T-Mobile USA, Inc.*, 2022 WL 4363582 (S.D. Fla. Sep. 21, 2022). The only issue on appeal regarding negligent misrepresentation in *BVS* was whether plaintiff's reliance on defendant's omissions was reasonable. 649 F. App'x at 661-62, 665.

CITATION TABLE C – FRAUD AND NEGLIGENT MISREPRESENTATION

Georgia: *Amin v. Mercedes-Benz USA, LLC*, 301 F. Supp. 3d 1277, 1296 (N.D. Ga. 2018) (one party has superior knowledge); *Jordan v. Flynt*, 240 Ga. 359, 366 (1977) (partial disclosure); *McCabe v. Daimler AG*, 948 F. Supp. 2d 1347, 1368-69 (N.D. Ga. 2013) (health and safety exception); *Hightower v. Century 21 Farish Realty*, 448 S.E.2d 271, 273 (Ga. Ct. App. 1994) ("same principles apply to both fraud and negligent misrepresentation cases."). **Respironics' response:** *Amin* did not hold that superior knowledge alone is sufficient to establish a duty. *Amin* requires superior knowledge ***and*** affirmative acts of concealment by the defendant, including during direct interactions not alleged here. 301 F. Supp. 3d at 1296. As to *Flynt, see* Reply at 17-18. As to *McCabe*, *see Rose v. Ferrari N.A., Inc.*, Civ. A. No. 21-cv-20772, 2022 WL 14558880, at *7-8 (D.N.J. Oct. 25, 2022) (applying Georgia law) (a plaintiff cannot plead a duty "based solely on the safety risks" but must also plead "a dependent relationship" with defendant).

Iowa: *Wright v. Brooke Grp. Ltd.,* 652 N.W.2d 159, 177 (Iowa 2002) (partial disclosure); *Cornell v. Wunschel,* 408 N.W.2d 369, 376 (Iowa 1987) (superior knowledge); *Union Cnty., IA v. Piper Jaffray & Co.,* 741 F. Supp. 2d 1064, 1089 (S.D. Iowa 2010). **Respironics' response:** As to *Wright*, *see* Reply at 17-18. *Cornell* addresses fraud, not negligent misrepresentation. As to *Union County*, *see* 741 F. Supp. 2d at 1109 (explaining duty to disclose for negligent misrepresentation claims limited to persons in the business or profession of supplying information to others).

Illinois: *Van Zeeland v. Rand McNally*, 532 F. Supp. 3d 557, 572-73 (N.D. Ill. 2021) (superior knowledge); *Toulon v. Cont'l Cas. Co.*, 877 F.3d 725, 737 (7th Cir. 2017) (partial disclosure); *Carlen v. Coloplast Corp*., No. 19-cv-1304, 2020 WL 3050752, at *6 (S.D. Ill. Jun. 8, 2020) (partial disclosure). **Respironics' response**: *Van Zeeland* held a duty to disclose may exist in the absence of a fiduciary relationship ***if*** there is a "special trust relationship" between the parties similar to a fiduciary relationship. 532 F. Supp. 3d at 572. That is absent here. *Accord Wigod v. Wells Fargo Bank, N.A.,* 673 F.3d 547, 573 (7th Cir. 2012) ("asymmetric information alone does not show the degree of dominance needed to establish a special trust relationship"). As to *Toulon* and *Carlen*, *see* Reply at 17-18.

Maryland: *Brass Metal Prod., Inc. v. E-J Enters., Inc.*, 984 A.2d 361 (Md. Ct. Spec. App. 2009) (partial disclosure). **Respironics' response**: *Brass Metal* considered whether there was a fiduciary or similar confidential relationship between the parties that created a duty to disclose. *Id.* at 387-88. The court did not hold or even consider whether a duty to disclose may exist under Maryland law in the absence of such relationship, or that a partial disclosure could give rise to such a relationship. Even if this exception was available (and it is not), *see* Reply at 17-18.

Massachusetts: *First Choice Armor & Equip., Inc. v. Toyobo Am., Inc.*, 717 F. Supp. 2d 156, 162 (D. Mass. 2010) (superior knowledge); *Stolzoff v. Waste Sys. Int'l, Inc*., 792 N.E.2d 1031, 1043-44 (Mass. App. Ct. 2003) (partial disclosure); *Broderick v. PNC Mortg. Corp*., Civ. A. No. 11-10047, 2013 WL 6909531, at *2 (D. Mass. Dec. 30, 2013) (partial disclosure); *Lynch v. Cotton*, 780 N.E.2d 488 (Mass. App. Ct. 2002) (superior knowledge). **Respironics' response**: "*First Choice* . . . did not hold that 'superior knowledge' alone creates such a duty—the plaintiff must also plead that the defendant made a misleading partial disclosure." *Rezendes v. Mitsubishi Motors N.A., Inc.*, No. 22-cv-10211, 2023 WL 1864405, at *5 n.1 (D. Mass. Feb. 9, 2023); *see also* Reply at 17-18. As to *Stolzoff* and *Broderick*, s*ee* Reply at 17-18. As to *Lynch*, there is no mention of a "superior knowledge" exception and, moreover, it is inapposite because it "[wa]s not a case of nondisclosure or total silence" but involved direct false statements by a broker to home purchasers. 780 N.E.2d 488, at *1.

CITATION TABLE C – FRAUD AND NEGLIGENT MISREPRESENTATION

Mississippi: *Poe v. Summers*, 11 So. 3d 129, 134 (Miss. 2009) (superior knowledge); *Welsh v. Mounger*, 883 So. 2d 46, 49 (Miss. 2004) (partial disclosure); *Shelter Mut. Ins. Co. v. Brown*, 345 F. Supp. 2d 645, 652 (S.D. Miss. 2004) (superior knowledge and partial disclosure). **Respironics' response**: *Poe* did not hold superior knowledge alone sufficient to establish a duty. *Poe* held a party must show (1) superior knowledge ***and*** (2) an affirmative act of concealment by defendant of a type not alleged by Plaintiffs here. 11 So. 3d at 134. As to *Welsh*, *see* Reply at 17-18. As to *Shelter*, plaintiff alleged defendant made a misleading partial disclosure, 345 F. Supp. 2d at 651-52, which Plaintiffs have failed to do here, *see* Reply at 17-18. Moreover, *Shelter* is further distinguishable because it involved parties—a homeowner and her insurer—who interacted directly. 345 F. Supp. 2d at 646.

North Carolina: *Hardin v. KCS Int'l, Inc*., 682 S.E.2d 726, 773 (N.C. Ct. App. 2009) (active concealment and superior knowledge); *Silicon Knights, Inc. v. Epic Games, Inc*., No. 07-CV-275, 2011 WL 1134453, at *13 (E.D.N.C. Jan. 25, 2011), report and recommendation adopted, 2011 WL 1134447 (E.D.N.C. Mar. 24, 2011) (principal difference in fraud and negligent misrepresentation is "intent to deceive"). **Respironics' response:** *Hardin* involves fraud, not negligent misrepresentation, and further, requires a plaintiff plead affirmative acts of concealment by the defendant, which Plaintiffs have not alleged. 682 S.E.2d at 773. *Silicon Knights* involved a duty based on a partial disclosure, *see* Reply at 17-18; *see also* CT E(3) (no viable claim for negligent misrepresentation claims in the personal injury context under North Carolina law).

New Jersey: *Ponzio v. Mercedes-Benz USA, LLC*, 447 F. Supp. 3d 194, 234 (D.N.J. 2020) (partial disclosure); *Amato v. Subaru of Am., Inc*., Civ. A. No. 18-16118, 2019 WL 6607148, at *21 (D.N.J. Dec. 5, 2019) (patrial disclosure). **Respironics' response**: *See* Reply at 17-18.

Nevada: *Dow Chem. Co. v. Mahlum*, 970 P.2d 98 (Nev. 1998), *abrogated on other grounds by GES, Inc. v. Corbitt*, 21 P.3d 11 (Nev. 2001) (superior knowledge); *Nelson v. Heer*, 163 P.3d 420, 426 (Nev. 2007) (partial disclosure). **Respironics' response**: *Dow* did not hold "superior knowledge" alone was sufficient to establish a duty and rejected plaintiffs' argument that it could. 970 P.2d at 111; *accord Las Vegas Metro. Police Dept. v. Harris Corp., M/A Com, Inc.*, No. 13-cv-01780, 2015 WL 895054 at *7 (D. Nev. Mar. 3, 2015) ("simply manufacturing or selling an alleged defective product is not enough to support the required relationship" for duty to disclose to exist) (citing *Dow*, 970 P.2d at 111)). As to *Nelson, see* Reply at 17-18.

New York: *In re Volkswagen Timing Chain Prod. Liab. Litig*., Civ. A. No. 16-2765, 2017 WL 1902160, at *21 (D.N.J. May 8, 2017) (superior knowledge). **Respironics' response:** The *Volkswagen* court relied on a New York case that only addressed a state law fraud claim, not negligent misrepresentation, to jointly address the plaintiffs' fraud and negligent misrepresentation claims. *Id.* at *19. Respironics cited New York case law clearly requiring a fiduciary or other special relationship to maintain a negligent misrepresentation claim. *See* CT E(2)(b). Moreover, the plaintiffs in *Volkswagen* pled (1) superior knowledge ***and*** (2) an affirmative act of concealment by defendant of a type not alleged by Plaintiffs here.

CITATION TABLE C – FRAUD AND NEGLIGENT MISREPRESENTATION

Ohio: *Stuckey v. Online Res. Corp.*, 819 F. Supp. 2d 673, 686-87 (S.D. Ohio 2011) (partial disclosure); *Andersons, Inc. v. Consol, Inc*., 348 F.3d 496, 506 (6th Cir. 2003) (applying Ohio law, defendant cannot make an affirmatively false statement). **Respironics' response:** For *Stuckey* and *Andersons, see* Reply at 17-18. Moreover, *Andersons* held that under Ohio law, a negligent misrepresentation claim only lies for an affirmatively false statement, not an omission. 348 F.3d at 506. Plaintiffs claim under Ohio law should be dismissed because Plaintiffs are only pleading omission-based negligent misrepresentation claims. *See* Opp. at 30-31.

Oregon: *Gregory v. Novak*, 855 P.2d 1142, 1144 (Or. App. 1993) (partial disclosure). **Respironics' response**: *See* Reply at 17-18.

Pennsylvania: *Gaines v. Krawczyk*, 354 F. Supp. 2d 573, 586 (W.D. Pa. 2004) (superior knowledge); *Volkswagen Timing Chain*, 2017 WL 1902160, at *19-20 (partial disclosure). **Respironics' response**: *Gaines* explained that Pennsylvania recognizes a duty in the context of real estate sales, but "[b]eyond this arena the duty does not ordinarily arise in a transaction unless there is a confidential or fiduciary relationship between the parties." 354 F. Supp. 2d at 586. As to *Volkswagen*, *see* Reply at 17-18.

South Dakota: *Maybee v. Jacobs Motor Co.*, 519 N.W.2d 341 (S.D. 1994) (partial disclosure). **Respironics' response**: *See* Reply at 17-18.

Texas: *White v. Zhou Pei*, 452 S.W.3d 527, 537-38 (Tex. App. 2014) (one party has superior knowledge); *Yoon v. Yoo*, No. 15-cv-303, 2016 WL 4801314 (N.D. Tex. Feb. 24, 2016) (partial disclosure); *Highland Crusader Offshore Partners, L.P. v. Lifecare Holdings, Inc.*, Civ. A. No. 08-CV-0102, 2009 WL 1065212, at *6 (N.D. Tex. Apr. 21, 2009) (health and safety exception); *Kirkbride v. Kroger Co*., No. 21-CV-0022, 2022 WL 2703960, at *8 (S.D. Ohio Jul. 12, 2022) (applying Texas law, partial disclosure); *Conestoga Tr. Servs., LLC, Tr. of Conestoga Tr. v. Focus Med. Underwriters, LLC*, No. 14-20-00302 CV, 2022 WL 599344, at *3 (Tex. App. Mar. 1, 2022) (superior knowledge). **Respironics' response**: *White* does not establish a superior knowledge exception and its discussion of partial disclosure is otherwise inapposite. *See* Reply at 17-18. As to *Yoon* and *Kirkbride*, *see* Reply at 17-18. Moreover, there is no mention of a health and safety exception in *Highland*. *Conestoga* involved affirmative misrepresentations, not omissions like at issue here. 2022 WL 599344, at *3.

Virginia: *Sonneveldt v. Mazda Motor of Am., Inc.*, 19-CV-01298, 2021 WL 4813753, at *6 (C.D. Cal. Jul. 29, 2021) (applying Virginia law) (superior knowledge); *Price Auto. II, LLC v. Mass Mgmt.,* No. 14-CV-00029, 2015 WL 300418, at *4 (W.D. Va. Jan. 22, 2015). **Respironics' response:** *Sonneveldt* did not hold that superior knowledge alone creates a duty. 2021 WL 62502, at *7 (dismissing common law fraud claim under Virginia law because pleading "superior knowledge" alone did not establish a duty to disclose). *Price* is distinguishable as it involved a direct buyer-seller relationship and the plaintiff alleged acts of affirmative concealment not pled here. 2015 WL 300418, at *7.

CITATION TABLE C – FRAUD AND NEGLIGENT MISREPRESENTATION

C(2) Negligent Misrepresentation (select jurisdictions): Respironics' Response to Cases Cited in Plaintiffs' Chart 8.

Arkansas: Restatement (Second) of Torts, § 311; *Holguin v. Celebrity Cruises*, No. 10-20215 CIV, 2010 WL 11602745, at *1 (S.D. Fla. Jun. 4, 2010); *see also Holiday Inn Fran., Inc. v. Hotel Assocs., Inc.*, 382 S.W.3d 6, 14 (Ark. Ct. App. 2011). **Respironics' response:** Plaintiffs offer no support that Arkansas has adopted § 311 and Respironics is aware of none. *Holguin* applies Florida law. *Holiday Inn* does not involve a claim for negligent misrepresentation.

Florida: *Holguin*, 2010 WL 11602745, at *1 (apply § 311 under Florida law); *Barrow v. Bristol-Myers Squibb*, 1998 WL 812318, at *45 (M.D. Fla. Oct. 29, 1998); *Albertson v. Richardson-Merrell, Inc.*, 441 So. 2d 1146, 1150 (Fla. Dist. Ct. App. 1983). **Respironics response:** The *Barrow* and *Holguin* courts did not hold that Florida has adopted § 311, and Respironics has not otherwise identified a case in which a Florida court has explicitly adopted § 311. *Albertson* did not involve a claim for negligent misrepresentation.

Idaho: *Clark v. Int'l Harvester*, 581 P.2d 784, 794 (Idaho 1978); *Packer v. Riverbend Commc'ns, LLC*, 468 P.3d 1283, 1287 (Idaho 2020). **Respironics' response:** *Clark* involved a traditional negligence claim, *see* 581 P.2d at 787, and *Packer* involved negligence and premise liability claims, *see* 468 P.3d at 1286. Moreover, in *Packer*, the lower court held that § 311 did *not* apply and the Idaho Supreme Court did not review this issue. 468 P.3d at 1286.

Indiana: *Volkswagen Timing Chain*, 2017 WL 1902160, at *21. **Respironics' response:** Respironics' position was not addressed in *Volkswagen.* Instead, for Indiana, the court considered whether there was an exception to the economic loss doctrine for tort claims. *Id.*

Maine: *Dow v. Maier*, No. Civ. A. 93-276, 2000 WL 33675683, at *3 (Me. Super. Ct. Mar. 15, 2000). **Respironics' response:** *See* MTD at CT E(4) (citing *Tardy v. Eli Lily and Co.*, No. CV 03-538, 2004 WL 1925536, at *4 (Me. Super. Ct. Aug. 3, 2004) (explaining Maine has adopted § 552(a)(1) as the appropriate standard for negligent misrepresentation claims).

Minnesota: *Cantonis v. Stryker Corp.*, Civ. No. 09-3509, 2010 WL 6239354, at *4 (D. Minn. Nov. 23, 2010), report and recommendation adopted, 2011 WL 1084971 (D. Minn. Mar. 21, 2011). **Respironics' response:** *Cantonis* involved a negligence, not negligent misrepresentation, claim.

North Carolina: *Hunter v. Guardian Life Ins. Co. of Am.*, 593 S.E.2d 595, 600 (N.C. Ct. App. 2004). **Respironics' response:** *Hunter* involved a dispute arising from the sale of an insurance policy and is distinguishable from *McBrayer v. Ethicon, Inc.*, No. 12-CV-00779, 2017 WL 73934, at *4 (S.D. W. Va. Jan. 6, 2017), which addresses a negligent misrepresentation claim in the personal injury context under North Carolina law. *See* MTD at CT E(3).

Virginia: *Barrigan v. Elite Funding*, Civ. A. No. 07-0951, 2009 WL 54514, at *4 (Jan. 6, 2009). **Respironics' response:** *See In re Allergan*, 537 F. Supp. 3d 679, 737 (D.N.J. Mar. 19, 2021) (applying Virginia law) (dismissing negligent misrepresentation claim brought under Virginia law).

CITATION TABLE D – CONSUMER PROTECTION

D(1) Personal Injury Damages Are Not Available Under the Consumer Protection Laws of at Least 13 States.

Respironics identified 14 states that do not allow recovery for personal injury claims under at least one of their respective consumer protection statutes. MTD at 35 & CT F(4). Plaintiffs concede this for 11 states, Opp. at 35 & Chart 12, these are: **Alaska**, **Florida (DUTPA)**, **Hawaii**, **Iowa**, **Maine (UTPA)**, **Nebraska (CPA)**, **Oregon**, **Pennsylvania**, **Tennessee**, **Texas**, ***and*** **Washington**.

Plaintiffs wrongly contend there is recovery for personal injury claims under laws of **New Mexico**, **Ohio**, and **South Carolina**. *See Pena v. Scrip, Inc.*, No. CV 11-1102, 2013 WL 12334164, at *7 (D.N.M. Mar. 22, 2013) ("The weight of authority indicates that personal injury damages are not available under the [New Mexico] UPA."); *Kelley v. Insys Therapeutics, Inc*., No. 18CV1774, 2019 WL 329600, at *7 (N.D. Ohio Jan. 25, 2019) (Ohio CSPA claims "involve economic harm to consumers not a supplier's misrepresentations which resulted in physical harm to a consumer").

D(2) Medical Devices Are Outside the Scope of Consumer Protection Laws in 24 Jurisdictions.

ALL (including **Alabama**, **Maine (UTPA)**, **West Virginia**)	Prescription medical devices are not "consumer goods." MTD at 35 & CT F(7). Plaintiffs cite no authority (Opp. at 35-36 & Chart 15) in arguing that only "implanted" prescription medical devices are not "consumer goods." A non-implanted prescription medical device is not a good for personal, family or household use and thus is not a consumer good . . . ." *Reeves v. PharmaJet, Inc*., 846 F. Supp. 2d 791, 798 & n.2 (N.D. Ohio 2012) (dismissing OCSPA claim); *Collins v. Davol, Inc.*, 56 F. Supp. 3d 1222, 1231 n.9 (N.D. Ala. 2014) (medical device "clearly inconsistent" with statutory definition of 'consumer good,' which are "goods that are used or bought for use primarily for personal, family, or household purposes."); *Otis-Wisher v. Medtronic, Inc*., 616 F. App'x 433, 435 (2d Cir. 2015) (affirming consumer protection claim could not be stated because medical device "is not available for consumer purchase, but rather was prescribed").
California (CLRA), **Dist. Of Columbia**, **Georgia (FBPA)**, **Illinois (CFA)**, **Indiana**, **Kentucky**, **Maryland**, **Michigan**, **Missouri**, **Montana**, **Ohio**, **Pennsylvania**, **Vermont**, **Virginia**, **West Virginia**	Plaintiffs cite consumer protection cases regarding ***drugs and homeopathic products—not prescription medical devices,*** Opp. at Chart 15, in wrongful support of prescription medical devices being within the scope of state consumer protection claims. *Compare Otis-Wisher*, 616 F. App'x at 435 (affirming medical device outside scope of Vermont Consumer Fraud Act) *with In re Wellbutrin XL Antitrust Litig*., 260 F.R.D. 143, 148 & n.2, 156 (E.D. Pa. 2009) (cited by Plaintiffs) (allowing Vermont Consumer Fraud Act claim regarding prescription drug).

CITATION TABLE D – CONSUMER PROTECTION

	Plaintiffs also argue that despite the West Virginia Supreme Court of Appeals' ruling that prescription drugs are not within the scope of the West Virginia Consumer Credit Protection Act "because the consumer can not and does not decide what product to purchase," *see White v. Wyeth*, 705 S.E.2d 828, 837-38 (W. Va. 2010), this case is somehow "distinguishable because CPAPs are personal use devices" despite the fact that they are prescription devices that the consumer cannot and does not decide what product to purchase.
Georgia (FBPA), **Hawaii**, **Ohio**, **Virginia**	Plaintiffs cite non-private right of action cases and settlement agreements asserting consumer protection claims, as support for medical devices being a consumer good. *See* Opp. at Chart 15, which includes: *Georgia ex rel. Carr v. Elite Integrated Med., LLC*, 533 F. Supp. 3d 1303, 1320 (N.D. Ga. 2021) (granting motion to remand FBPA claims concerning stem cell products brought by Georgia Attorney General under Ga. Code Ann. § 10-1-397 (Actions by Attorney General for equitable relief)). *People v. Med. Device Bus. Servs. f/k/s Depuy*, No. 450069/19, 2019 N.Y. Misc. LEXIS 12666 (N.Y. Sup. Ct. Feb. 5, 2019) (consent order settlement with New York Attorney General with implanted device manufacturer listing, *inter alia*, Hawaii consumer protection statute and reciting denial of a violation of the cited statutes). *State ex rel. Dewine v. Janssen Pharm., Inc.*, No. 12CV010992, 2012 Ohio Misc. LEXIS 17878 (Ohio Ct. Com. Pl. Franklin Cnty. Sep. 10, 2012) (settlement agreement of Ohio Consumer Sales Practices Act claim regarding prescription drugs brought by Ohio Attorney General). *Commonwealth ex rel. Herring v. Teva Pharms. USA, Inc.*, 107 Va. Cir. 44 (Va. Cir. Ct. 2020) (Virginia Consumer Protection Act claims regarding prescription drugs brought by Virginia Attorney General under Va. Code 59.1-203 (Restraining prohibited acts) and other statutes)

D(3) <u>The Consumer Protection Statutes of at Least 30 Jurisdictions Require Factual Pleading of Reliance.</u>

Respironics identified 37 states whose consumer protection statutes "require factual pleading of causation and/or reliance." CT D(3). Plaintiffs concede 29 jurisdictions require reliance pleading to state a consumer protection claim, Opp. at 30 & n.33; these are: **Alabama**, **Arizona**, **Arkansas**, **California (UCL, CLRA, FAL)**, **Georgia (FBPA)**, **Hawaii (UDAP)**, **Indiana**, **Louisiana (UTPCPL)**, **Massachusetts**, **Minnesota (PCFA)**, **Mississippi**, **Missouri**, **Nevada**, **New Hampshire**, **North Carolina**, **Oklahoma**, **Oregon**, **Pennsylvania**, **Rhode Island**, **South Carolina**, **South Dakota**, **Tennessee**, **Texas**, **Utah (CSPA)**, **Vermont**, **Virginia**, **West Virginia**, **Wisconsin**, and **Wyoming**.

CITATION TABLE D – CONSUMER PROTECTION

Plaintiffs wrongly contend reliance pleading not required under **Colorado**, **Connecticut**, **Illinois**, **Kentucky**, **Maryland**, **New Jersey**, or **New Mexico** law, and **California** law presumes reliance with material misrepresentations alleged. *See Richards*, 2022 WL 657568, at *29 (to state a Maryland CPA claim, consumer must allege "an unfair or deceptive practice or misrepresentation that . . . causes them actual injury"); *see also* CT D(3) (identifying jurisdictions in which Plaintiffs are required to allege causation and/or reliance).

D(4) Scienter Must Be Pled with Specificity Under the Consumer Protection Statutes of at Least 14 Jurisdictions.

Respironics identified 19 states whose consumer protection statutes require pleading of scienter with specificity. CT D(4). Plaintiffs concede 13 jurisdictions require scienter pleading, Opp. at 31 & n.40; these are **Alabama**, **Colorado**, **Iowa**, **Kansas**, **Kentucky**, **New Mexico**, **North Dakota**, **Oklahoma**, **South Dakota**, **Utah (CSPA)**, **Virginia**, **Wisconsin**, and **Wyoming**.

Plaintiffs wrongly contend scienter pleading with specificity not required under **Arizona**, **Illinois**, **Nevada**, or **Pennsylvania** law, and "not all consumer protection theories alleged under **Arkansas** and **Maryland** law require knowledge." *See Hart v. Amazon.com, Inc.*, 191 F. Supp. 3d 809, 822 (N.D. Ill. 2016) (to state an Illinois CFA private cause of action, plaintiff must allege "defendant's intent that plaintiff rely on the deceptive or unfair practice"), *aff'd*, 845 F.3d 802 (7th Cir. 2017); *see also* CT D(4) (identifying jurisdictions in which consumer protection statute plaintiffs must allege scienter with specificity).

CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2023, the foregoing document was electronically filed with the Clerk of the Court and served upon counsel of record through the Court's ECF system.

/s/ John P. Lavelle, Jr.
John P. Lavelle, Jr.